Ethical guidelines and procedures

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Table of Contents

List of Figures

List of Tables

1. Executive Summary

The ethical evaluation and research of the legal framework to be considered and applied throughout the HEIDI project starts from the beginning of the project activities (e.g., identification of user needs, definitions, designs, etc.), goes on all over the project implementation, and will produce initial recommendations for legal framework and standardization (D5.4). Ethical and legal research compliance relative to the execution of tests and validations, especially the ones including human participation, is also significant for the quality of research results.

Task 5.1 investigates the Ethical issues and procedures for tests involving participants. We will identify the ethical principles and standards to establish an ethics protocol ensuring that HEIDI meets the requirements of responsible research practice with specific reference to the performance of tests involving human participants in project activities. Ethical considerations and specific procedures will be identified and discussed.

The present deliverable, D5.1 Ethical guidelines and procedures, is organized as follows: Section 3 presents an analysis of the ethical and legal framework that should be applied during HEIDI activities and validations, including i) ethical issues in research; ii) legal framework for ethics in Horizon Europe projects; and (iii) ethics to consider for participation of human subjects in project activities. In Section 4 we present the overall HEIDI methodology for involving subjects in the testing and validation phases: exploratory and evaluation studies, and the real-world demonstrations. Also, we describe considerations on the use of IT devices and/or driving simulators, the procedures and criteria used to identify/recruit participants, the methodologies applied to ensure privacy, confidentiality and an adequate data collection and storage. Furthermore, information related to the cooperation with the Ethics Advisor and the involvement of Institutional/Local Ethics Review Boards is explained in section 4.4.

Keywords: Ethics, testing, validation, human participants, data management.

2. Objectives

The primary objective of this deliverable is to report about ethical and legal considerations, principles and standards analysed for the HEIDI project, as well as the consolidation of the strategy, guidelines, and requirements to be followed in project activities and with special focus on the validations in real world scenarios. As part of WP5, this objective complements HEIDI's main objectives 3 and 4 related with the development of suitable validation methods for assessing fluid, cooperative HMI solutions and the elaboration of recommendations for regulation, standardisation, and development of adaptive internal and external HMIs, respectively.

To reach this objective, we performed an analysis and identification of the ethical principles and standards related to ethics in research studies, participation of subjects in testing, EU regulations concerning privacy and data management that ensure that HEIDI meets the requirements of responsible research practice with specific reference to the performance of tests involving human participants.

3. Analysis of the ethical and legal framework

3.1 Ethical issues in research considering human participation

The European Commission request researchers consider ethics at the conceptual stage of the proposal and during the complete lifespan of the project, especially in Research and Innovation Actions, resulting in the enhancement of the research quality. All the activities related to validations where the participation of human subjects is expected must comply with ethical principles, as well as relevant national, EU, and international legislations.

In this sense, the EC published the Golden Rules of Ethical Research Conduct [1], as part of their methodology and practical advice to researchers to not forget ethical research. These rules include the following ones that are applicable to HEIDI approach:

- Respect the integrity and dignity of persons.
- Clearly communicated risks to the subjects involved ("do no harm" principle).
- Recognise the rights of individuals to privacy, personal data protection and freedom of movement.
- Informed consent and continuous dialogue with research subjects.
- Not going beyond stated objectives.
- Try to prevent being openly available for misuse or malignant dual use by terrorists or military organisations.
- Treats societal concerns seriously - a researcher's first obligation is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity.
- Build on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from your research must be considered.

The consortium must pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection.

3.2 Legal framework for ethics in Horizon Europe projects

During project execution, consortium partners will comply with the ethics and security requirements as set out in the Grant Agreement (article 14) and in international conventions and declaration.

As stated in HEIDI Grant Agreement, the European Code of Conduct for Research Integrity will be fully addressed by consortium partners in all the activities related to the execution of the project. This code of conduct "*serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings*." In the last revision (2017) [2] the code addresses emerging challenges related to technological developments, open science, citizen science, and social media, among other areas such as violations of research integrity (e.g., falsification and plagiarism) and procedures to be followed in the event of those violations.

Under the code of conduct researchers are invited to follow good research practices are based on the following fundamental principles of research integrity [2]:

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

Furthermore, there are international legal frameworks important for compliance with ethical principles including the ones requested by the code of conduct and the ones related to the privacy and security of personal data. The following are the principal international conventions and declarations that will be taken into consideration during the project activities:

- Charter of Fundamental Rights of the European Union (in particular Art. 8 on the protection of personal data)
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – GDPR)

Subsections 3.2.1 and 3.2.2 present a brief summary of the objectives of these regulations and the principles applicable to HEIDI research activities.

3.2.1 Charter of Fundamental Rights of the European Union

This document gathers the fundamental rights regarding human dignity, integrity, freedom, equality, liberty and security, solidarity, citizens' rights, and justice to be shared, fostered, and protected by every Member State of the European Union, as well as general provisions governing the interpretation and application of the Charter [3]. Studies involving human participants must adhere to research ethics and ethical values. These values are held by the researchers and engineers performing research involving human participants and are practiced during the duration of project activities.

Along with these human fundamental rights, the charter gathers two rights specifically related to the protection of personal data and intellectual property [3]:

- **Article 8 Protection of personal data**
  1. *Everyone has the right to the protection of personal data concerning him or her.*
  2. *Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.*
  3. *Compliance with these rules shall be subject to control by an independent authority.*
- **Article 17 Right to property**
  1. *Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.*

2. *Intellectual property shall be protected.*

3.2.2 General Data Protection Regulation (GDPR)

The European legal framework for ethics in Horizon Europe projects comprises the General Data Protection Regulation 2016/679/EU of 27 April 2016 [4]. The GDPR main objectives are focused on rules related to the "*protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data*", the protection of "f*undamental rights and freedoms of natural persons and in particular their right to the protection of personal data",* and the restrictions of the free movement of personal data within the Union.

The main articles and principles, under this regulation, to be considered by all partners of the HEIDI consortium in project activities where personal data is used, stored and processed are the following:

- **Lawfulness, fairness and transparency (article 5(1)(a))**

  1. *Personal data shall be:*

     (a) processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency')

- **Legitimate purpose (article 5(1)(b))**

  1. *Personal data shall be:*

     (b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation')

- **Data minimization (article 5(1)(c))**

  1. *Personal data shall be:*

     (c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')

- **Accuracy (article 5(1)(d) GDPR)**

  1. *Personal data shall be:*

     (d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy')

- **Storage limitation (article 5(1)(e))**

  1. *Personal data shall be:*

     (e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation')

- **Integrity and confidentiality (article 5(1)(f) GDPR)**

1. *Personal data shall be:*

   (f) processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality')

- **Pseudonymisation techniques**

Article 4 GDPR, defines personal data as:

(5) 'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person;

Article 32 (1):

Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, the controller and the processor shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk, including inter alia as appropriate:

(a) the pseudonymisation and encryption of personal data;

(b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;

(c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;

(d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

- **Consent and other legal basis for lawful data processing**

Article 6 - Lawfulness of processing:

1. *Processing shall be lawful only if and to the extent that at least one of the following applies:*

   (a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

Article 7 - Conditions for consent:

1. *Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.*
2. *The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.*

Details on how the data will be managed during project activities will be provided in the Initial Data Management Plan deliverable (D9.1) document.

4. HEIDI approach

The HEIDI project, within WP5 activities, will design and evaluate methods for the validation of the fluid and cooperative HMI system developed in WP2, WP3 & WP4. These methods will allow a more holistic evaluation of the HEIDI system by also incorporating the dynamic aspects of driver-pedestrian interactions. The following subsections present the overall approach that will be followed during the validation activities, considering the specific requirements and considerations based on the characteristics of the HEIDI validation studies.

4.1 Overall methodology for involving users in HEIDI research activities

The testing of the methods will follow a stepwise approach whereby first, methods for evaluating the HEIDI components (internal and fluid HMI and eHMI) will be separately assessed. Subsequently, these methods will be refined and integrated in a co-simulation test with drivers and pedestrians in-the-loop for the evaluation of the complete HEIDI system. In the different experimental studies, the fluid internal and external HMIs and the cooperative HMI, designed during the project, will be compared with other existing or proposed static, i.e., non-adaptive and non-cooperative HMI concepts. In this way, the possible beneficial effects of HEIDI HMIs can be highlighted and quantified.

During the HEIDI project, 4 exploratory studies and 8 evaluation studies are planned. The following subjection presents HEIDI's exploratory and evaluation studies. Table 4-1 and Table 4-2, present a summary of the objective, use case addressed, topic, measurements, and outcomes of the exploratory and evaluation studies.

In none of the HEIDI studies will human participation experience physical interventions, no biological samples will be collected. None of the experiments requires invasive methods. The HEIDI studies involve collecting observational data about human participants driving a vehicle in simulated or real-world environments. For observations in a real environment, safety conditions will be explicitly analysed and documented prior to study conduct to ensure safety of the involved participants and experimenters. No personally identifiable information will be associated directly with the collected data and the collected data will not be able to be associated with the human participants.

Human participants involved in the studies will correspond to the defined types of road users considered in the HEIDI project in the light of their interactions with automated vehicles with different levels of automation defined in deliverable D1.1 - Description of user needs: (i) vulnerable road users: older pedestrian, adult pedestrian (over 18+); (ii) ego-driver; and (iii) external drivers.

4.1.1 Exploratory studies

Table 4-1: HEIDI exploratory studies information

Kind of study	Obj. addressed	Use case addressed	Main measurements & outcomes
Study 1: Initial test of the fluid iHMI and Osmotic Layer (P: VIF)			
First experimental study testing the fundamental principles of the fluid iHMI in combination with the Osmotic Layer and comparing it with a baseline internal HMI.			
Simulator	1 & 2	UC1	Comparison between baseline HMI (non-adaptive) and fluid iHMI in terms of safety, acceptance, trust, and usability, evaluated both objectively, looking ad driving safety

			performance, a subjectively with questionnaires or similar tools to be adapted.
Study 2: Initial test of driver monitoring & prediction algorithms (P: VIF, UAH)			
Small-scale simulator study to test & adapt driver monitoring & prediction algorithms.			
Simulator	2	UC1	Comparison between state-of-the-art driver monitoring algorithm, based on eye movement and steering wheel metrics, and advanced algorithm with driver's behaviour and intention prediction component. Some measurements include: objective driving performance, subjective acceptance and trust rate.
Study 3: Initial test of fluid eHMI (P: RUAS, MAR)			
First experimental study testing the fluid eHMI and comparing it with a baseline external HMI.			
Simulator	1 & 2	UC2	Comparison between baseline eHMI (non-adaptive) and fluid eHMI in terms of safety, acceptance, trust, and usability. Acceptance, trust, and usability will be evaluated based on questionnaires (subjective measurement), while safety will be evaluated based on, e.g., reaction time (objective measurement).
Study 4: Initial test of pedestrian recognition & prediction algorithms (P: RUAS, MAR)			
Small-scale simulation study to test & adapt pedestrian recognition & prediction algorithms. Simulation of sensory data as development step.			
Computational study	2	UC2	Interaction metrics.

(P = Partners involved; UC1: internal HMI for regular, distracted and older drivers; UC2: External HMI, multiple pedestrians at signalised and no signalised crossings; UC3: Fluid HMI: different cooperative HMI strategies)

4.1.2 Evaluation studies

Table 4-2: HEIDI evaluation studies information

Kind of study	Obj. addressed	Use case addressed	Main measurements & outcomes
Study 5: Small-scale test of fluid iHMI for older drivers & distracted drivers (P: VIF, VTI)			
Small-scale test of iHMI described within UC1 in a simulator environment. Main objective to test validation method.			
Simulator	1, 2 & 3	UC1	Comparison between baseline HMI (non-adaptive) and fluid iHMI in terms of safety, acceptance, trust, and usability, evaluated both objectively, looking ad driving safety performance, a subjectively with questionnaires or similar tools to be adapted.
Study 6 - Small-scale test of eHMI for groups of pedestrians (P: RUAS, VTI)			
Small-scale test of eHMI described within UC2. Main objective to test validation method.			
Simulator	1, 2 & 3	UC2	Evaluation of eHMI to communicate with groups of pedestrians. Acceptance, trust, and usability will be evaluated based on questionnaires (subjective

			measurement), while safety will be evaluated based on, e.g., reaction time and correct identification and response of identified person(s) of interest (objective measurement).
Study 7: Small-scale test of the cooperative HEIDI system (P: VTI, RUAS, HRI-EU)			
Small-scale test of the HEIDI cooperative HMI described in UC3. Test of validation method for the cooperative HEIDI system using networked simulators (co-simulation). Refinement of validation method based on preceding study 5 & 6.			
Simulator	1, 2 & 3	UC3	Different methods will be tested to assess the performance of the HEIDI cooperative and adaptive HMI in a multi-simulation environment where two participants (a pedestrian and a driver) will interact in different traffic situations. The effects of the HEIDI cooperative and adaptive HMI system on the safety, efficiency and comfort of the interaction will be compared to other non-adaptive and/or non-cooperative systems. Measurements will be subjective (e.g., likert scales), behavioural (e.g., crossing time/distance) and physiological (e.g., electrooculograms or electrocardiogram)
Study 8: Evaluation test of iHMI (P: BMW, NISYS, VIF)			
Evaluation test of the finalised iHMI concept in conjunction with Osmotic Layer. Assessment of safety, driver distraction, usability.			
Controlled real-world environment	1, 2 & 3	UC1	Comparison between baseline HMI (non-adaptive) and fluid iHMI in terms of safety, acceptance, trust, and usability, evaluated both objectively, looking ad driving safety performance, a subjectively with questionnaires or similar tools to be adapted. Integration of driver monitoring and prediction algorithm.
Study 9: Field demonstration of iHMI & Osmotic Layer (P: BMW, NISYS, VIF)			
Final field demonstration of iHMI prototype in combination with the Osmotic Layer in a passenger vehicle.			
Controlled real-world environment	1, 2 & 3	UC1	N/A - this is a live demonstration
Study 10: Evaluation test of eHMI (P: MAR, RUAS, UAH)			
Rate the effectiveness & effect of the eHMI on distraction of pedestrians.			
Controlled real-world environment	1, 2 & 3	UC2	Visibility, recognition, understanding.
Study 11: Field demonstration of eHMI (P: MAR, RUAS, UAH)			
Final field demonstration of eHMI prototype in a passenger car.			
Controlled real-world environment	1, 2 & 3	UC2	N/A - this is a live demonstration
Study 12: Evaluation test of cooperative HEIDI HMI (P: VTI, RUAS, HRI-EU, VIF)			
Evaluation test of the finalised cooperative HMI. Assessment of safety & usability.			
Simulator	1, 2 & 5	UC 1, 2 & 3	The performance of the HEIDI cooperative and adaptive HMI in a multi-simulation environment where two

			participants (a pedestrian and a driver) will interact in different traffic situations. The effects of the HEIDI cooperative and adaptive HMI system on the safety, efficiency and comfort of the interaction will be compared to other non-adaptive and/or non-cooperative systems. Measurements will be subjective (e.g., likert scales), behavioural (e.g., crossing time/distance) and physiological (e.g., electrooculograms or electrocardiogram)

(P = Partners involved; UC1: internal HMI for regular, distracted and older drivers; UC2: External HMI, multiple pedestrians at signalised and no signalised crossings; UC3: Fluid HMI: different cooperative HMI strategies)

4.2 Considerations on the use of IT

4.2.1 Devices and/or Driving Simulators

Some HEIDI studies will use IT devices and/or driving simulators that will use interaction technologies such as large screens, touch screens, virtual reality technology, HMIs, etc.

HEIDI partners and participants involved in validation studies will be aware of the risks/discomforts that could be generated by the specific characteristics of driving simulations. Detailed information related to discomforts/risks that could be present during the execution of the tests will be previously informed within the “Participant Information Sheet” (see Annex 1) and the use of these technologies will need consent from the participant.

The main concern when using driving simulators is simulation sickness, which is a particular form of motion sickness, that may be produced in some people. Simulator-based studies essentially need to understand the causes of motion sickness, and therefore Simulation Sickness (SS) to ensure the feasibility and validity of the study. SS could be classified in two types based on the characteristics of the static simulator environments, where only visual motion is presented [5]:

- Simulated Car Sickness (SCS): motion sickness produced by a simulator that is comparable to the one that could result from vehicle motion during real driving.
- Simulator-Induced Sickness (SIS): refers to motion sickness that are produced from false or missing motion cues, for example: differences between simulation and real driving motion, or discrepancies between motion cues and previous experiences as reference.

To avoid and/or lower the level of simulation sickness, the desire study scenario has to present a simulation environment that minimize the differences, between the real driving motion and the simulated scenario, that could be present to generate SIS and to closely approximate SCS to real car sickness.

In a general view, subjects participating in HEIDI validations may experience headaches while performing the driving simulations. These headaches (if they occur) are of the same type one might experience during standard simulator training, when studying, or using computers for extended periods. The study procedures are designed to reduce at minimum the level of discomfort, in conformity to the investigated aims. If subjects experience any discomfort, or

otherwise wish to terminate the experiment, they will be able to do so at any time without penalty.

4.2.2 Sensing algorithms

HEIDI will develop novel AI-based (Artificial Intelligence-based) functions for identifying pedestrians' category (e.g., older adults) and ability using visual information. Furthermore, HEIDI will provide driving driver state modelling, based on existing models, and extended by driver behaviour prediction algorithms, which sense based on current external context and vehicle data, what actions the driver is likely to do next.

As stated in the Grant Agreement (GA) these AI-based systems will be developed by using last generation Deep Learning architectures based on Convolutional Neural Networks. All the data collected by HEIDI will be stored in anonymised format, so that data privacy will be always respected. No images will be made public, and the system will only store the embedded, pre-processed features obtained from the original images during the learning process. Details and specifications about these algorithms will be provided in the "Participant Information Sheet" (Annex 1 – Participant Information Sheet template).

The focus of the HEIDI project is to develop adaptive HMI solutions which are used by a broad group of users. Therefore, gender aspects will be important to address during the project. This is especially relevant in the four following points: First, characteristics of the user group in terms of biological sex, but also in a broader sense in terms of age or user capabilities are at the core of the HEIDI HMI solutions. For example, the fluid iHMI also focuses on supporting elderly drivers when support is needed. Or, the HEIDI pedestrian sensing algorithms are specialised to sense and classify the capabilities of pedestrians, such as driving in a wheelchair or being able to walk normally.

Second, gender sensitive methodologies will be used in the design of the HEIDI HMI solutions to assess gender specific needs. This will be taken into consideration during the assessment of requirements and user needs within WP1 and during the conceptualisation of the sensing algorithms to be used for the iHMI and eHMI, within WP2, WP3 and WP4 activities. It is highly important to prevent algorithmic bias [6][7][8] by ensuring un-biased training data sets in terms of gender, age, and capabilities. If a potential effect is identified, it will be assured that the training data set is unbiased in this regard (e.g., during the data-generating and preparation process).

There might be other ethical considerations that specifically would arise during the design and testing of the algorithms that will be addressed in more details in the documents that will be prepared for each study to pass the local/institutional ethics review boards.

4.3 Considerations regarding unusual health-related observations or medical emergencies during the tests

If any unusual measurement coming from physiological parameters or health measures (e.g., heart rate, visual acuity, etc.) collected during the tests is observed the principal investigator of the study will check if the participant provided consent to be informed about it. If there is any health emergency coming from this observation the principal investigator is encouraged to call emergency services and provide medical attention to the participant.

If a participant feels sick or has any health issue during the execution of the tests, the principal investigator should provide prompt health care and call emergency services if necessary.

4.4 Procedures and criteria used to identify/recruit research participants

The following subsections present the procedures stablished to identify/recruit research participants. In addition, Annex 3 presents a “Guide for investigators” with the process to follow during the tests to involve participants to the studies.

4.4.1 Participants selection

In general terms, the recruitment of participants for the validation studies must follow a methodological criterion that ensures that no form of discrimination occurs, as well as providing mechanisms to give free informed, and explicit consent before the participation of human subjects. The consortium will have to ensure the physical and psychological integrity of these participants during their collaboration in the project activities, in particular concerning vulnerable road users (older adults, disable users, etc.).

The following are the procedures that partners involved in the recruitment process of the validation studies will follow to recruit participants:

Table 4-3: HEIDI recruitment process by partner

Partners	Recruitment process
VIF	Participants are usually recruited using online tools at local University and posting advertisements at known locations. Participants need to possess a valid driving license for at least three years and have normal or corrected-to-normal vision. Before taking part in the study, they have to sign an informed consent form. Specific requirements are further described in the recruitment forms according to the different studies. Participants receive a monetary incentive for their participation.
VTI	Participants for the studies carried out at VTI (Linkoping Office, Sweden) will be selected through advertisements published on VTI's official website (www.vti.se) and disseminated through its social networks on Facebook and Twitter. Interested volunteers will be redirected to a form asking information on demographics and driving experience. Volunteers who meet the minimum requirements for the study will then be selected and contacted by one of the researchers. An equal distribution of men and women will be ensured in the sample. Participants will receive prior information on the objectives and characteristics of the study, as well as on the possible risks. During participation, they will fill in an informed consent form and will receive financial compensation.
MAR	Participants are recruited mainly from our pool of employees and due to the cooperation with Reutlingen University from their pool of students. The main communication method will be email listings or public announcements. The pool of participants shall enclose an equal number of female and male participants.

4.4.2 Informed Consent and Participant Information Sheet

Prior to participating in the experiments, participants will give their written informed consent after having been fully informed about what the research involves and can withdraw the consent at any time. None of the experiments planned within the research proposal will include participants who are particularly vulnerable or unable to give informed consent.

Annex 1 and Annex 2, present common templates of the Participant Information Sheet, which will include all the details about the security aspects of the study activities and concerning the data management of their personal data, and the Informed Consent document which the participants will sign approving be involved in the study.

4.5 Data collected and processed during the studies

There are two main types of data defined in the GDPR that requires special attention when is collected, stored, and processed during the studies: personal data and sensitive data.

Article 4 of the GDPR, defines **personal data** as:

"(1) *'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;*"

In the same way, the GDPR defines **sensitive data** as data that is highly relevant because they are subject to a higher level of protection including: genetic, biometric and health data, as well as personal data revealing racial and ethnic origin, political opinions, religious or ideological convictions or trade union membership.

The HEIDI project approach involves the collection, storage, and/or processing of personal data during the validation phase. The data will be collected for internal use and not intended for long-term preservation after the end of the project. Consortium partners will pay special attention to the security, privacy, and confidentiality of the data handled in fully compliance with the applicable regulations at national and European levels, specifically to the EU GDPR 2016/679 regulation for the European Union.

The data collected during the validation phase might include files containing personal data (e.g., name, age, gender), general information about the participant activities (physical fitness, videogames, etc.), questionnaires related to the experiment, videos, kinematic traces saved motion captures system, simulation related variables (e.g., steering wheel and pedal position, etc.), and sensitive data such as: eye movements, physiological signals (skin conductance, heart rate). The research does not involve invasive and/or physical stimuli, scans or x-rays.

The following is a summary table of the HEIDI studies indicating the type of data that will be collected, stored and/or processed.

Table 4-4: HEIDI studies' type of data collected, stored and/or processed

HEIDI case studies			Use case	Data collection		
Studies	**Involved Partners**	**Type**	**UC1, UC2, UC3**	**Personal Data**	**Sensitive Data**	**Type of data**
Exploratory studies						
Study 1 – Initial test of the fluid iHMI and Osmotic Layer	VIF	Simulator	UC1	YES	YES	age, attention level, visual acuity

Study 2 – Initial test of driver monitoring & prediction algorithms	VIF, UAH	Simulator	UC1	YES	YES	age, attention level, visual acuity
Study 3 – Initial test of fluid eHMI	RUAS, MAR	Simulator	UC2	YES	YES	motion capture data, sensor data, age, physical disabilities, probably also attention level
Study 4 – Initial test of pedestrian recognition & prediction algorithms	RUAS, UAH	Computational study	UC2	YES	YES	age, attention level, physical disabilities
Evaluation studies						
Study 5 - Small-scale test of fluid iHMI for elderly drivers & distracted drivers	VIF, VTI	Simulator	UC1	YES	YES	age, attention level, visual acuity
Study 6 - Small-scale test of eHMI for groups of pedestrians	RUAS, VTI	Simulator	UC2	YES	YES	motion capture data, sensor data, age, physical disabilities, probably also attention level
Study 7 - Small-scale test of the cooperative HEIDI system	VTI	Simulator	UC3	YES	YES	demographic data (age, gender), driving experience, attention level, visual acuity, type of disability
Study 8 - Evaluation test of iHMI	BMW, NISYS, VIF	Controlled real-world environment	UC1	YES	YES	age, attention level, visual acuity
Study 9 - Field demonstration of iHMI & Osmotic Layer	BMW, NISYS, VIF	Controlled real-world environment	UC1	N/A	N/A	N/A
Study 10 - Evaluation test of eHMI	MAR, RUAS, UAH	Controlled real-world environment	UC2	YES	YES	Age, height gender, visual acuity, attention level
Study 11 - Field demonstration of eHMI	MAR, RUAS, UAH	Controlled real-world environment	UC2	N/A	N/A	N/A
Study 12 – Evaluation test of cooperative HEIDI HMI	VTI, RUAS, HRI-EU, VIF	Simulator	UC3	YES	YES	demographic data (age, gender), driving experience,

						attention level, visual acuity, type of disability

4.5.1 Confidentiality & Data management

The following are the key principles of HEIDI data use and management that will be followed to ensure confidentiality and privacy during data management. More in-depth details of data management mechanisms and processes for data collection, storage, protection, retention, and destruction, that will be implemented in HEIDI's activities, will be described in the Initial Data Management Plan (D9.1).

1. The partners will comply with the laws in each partner country with respect to the right for privacy and the confidentiality of data and in compliance with the GDPR.
2. Data for the project will be stored within trusted data centres and only transferred when needed.
3. There will be no transfer of personal data to other partners and parties inside or outside of the European Union. If the exchange is needed for research purposes partners should follow EU rules for the exchange of data between EU member states.
4. Participation in research studies of HEIDI will not result in any loss of privacy, as no one other than the investigator(s) of the project will have access to participants' personal information: data will be securely stored and analysed anonymously.
5. The collected data will be exclusively used for research purposes and - under no circumstances - used for any commercial purposes.
6. Any project result or confidential information that is provided, disclosed or otherwise made available between the partners will not include personal data.
7. The transmission of data through scientific publications and presentation at meetings, workshops, newspapers, etc., will be done in a completely anonymous manner and regards primarily aggregated and/or statistically processed data.

4.6 Ethics Advisor and Institutional/Local Ethics Review Boards

4.6.1 Cooperation with the Independent Ethics Advisor

To ensure ethical compliance throughout the entire HEIDI project, the consortium has appointed an Ethical Advisor (EA) as independent expert, with a relevant academic and professional ethics and legal background, for contributing to the ethical and legal implications to have in consideration during the validation studies of the solutions, and the protocols to carry out these tests with users.

The EA will foster the awareness of standards on European ethical and legal value-based framework in personal data protection (GDPR), not-discriminatory conduct (Charter of Fundamental Rights of the European Union), and prevention of conflicts of interest (European Code of Conduct for Research Integrity). The EA will advise Consortium to promote a research environment, within HEIDI developments and tests, characterized by high ethical standards and in full compliance with applicable regulations and rules. Given the nature of this position the EA is expected to operate completely independently and provide independent judgement.

The EA is responsible for:

- Give advice and assistance on ethics to the consortium for the proper management of all ethics procedures in HEIDI's activities.
- Be engaged to provide feedback on whether the project may involve ethical considerations.
- Support, validate and review the present document (deliverable 5.1 – Ethical guidelines and procedures) for ethical compliance established for the validations.
- Provide opinions and feedback on Initial recommendations to D5.4 Legal Framework and Standardisation.

4.6.2 Institutional/Local Ethics Review Boards

In addition to the ethical revision coming from the EA, HEIDI studies will pass through institutional/local ethics review boards in order to validate the methodology that will be followed in the study and to receive ethical approval to conduct the validations. The local ethics review boards that will be part of this process are: (i) VIF Internal Review Board (AT), and the (ii) Swedish Ethical Review Authority (SE). Partners participating in the studies designed for the validation phase of HEIDI developments are encouraged to submit the methodology of the study to, at least, one institutional/local ethics review board to ensure compliance with ethics and local rules.

The following diagram (*Figure 4-1*) presents an example of the internal review process that will be applied to the appraisal of a study involving human participants. In case of recommended mitigations, the study proposal needs to address them and is resubmitted until unconditional approval is achieved.

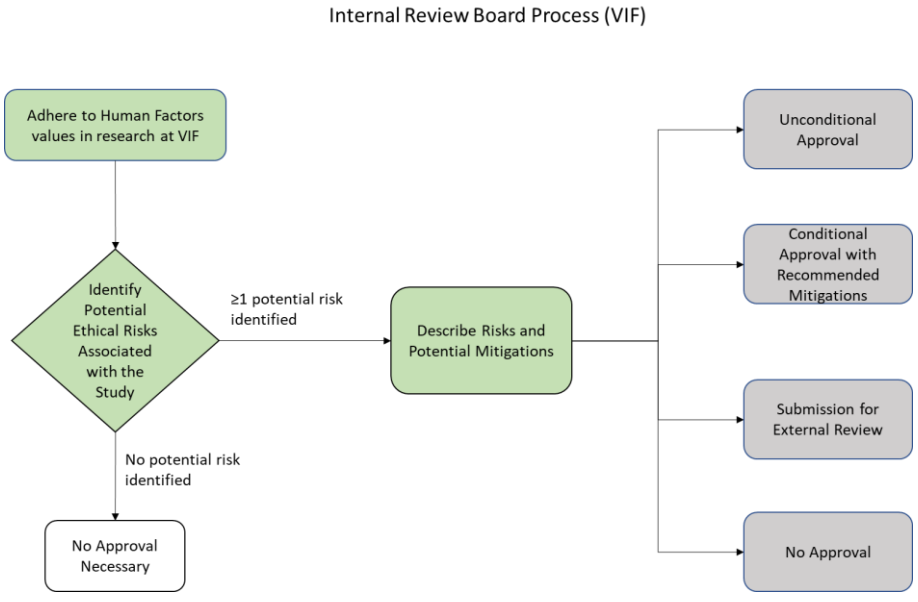

Figure 4-1: Internal Review Board process at VIF and possible outcomes

5. Conclusion

This deliverable is the first major step toward the establishment of the validation strategy of the project. It provides all partners with a set of guidelines they could consult to ensure they comply with the project's ethics policy. An analysis of current ethical and legal frameworks applicable to HEIDI validations was presented taking into consideration the implication of human participants in the studies. Furthermore, a brief description of the overall approach of HEIDI exploratory and evaluation studies was provided and will be later updated and complemented in deliverable D5.2 – State of Art on validation methods for cooperative and adaptive HMI solutions, including current methods to evaluate internal and external HMIs and users' interactions in real and virtual settings. Procedures and guidelines on how data needs to be collected, stored, and processed is provided and will be complemented and explained with more details in the Initial Data Management Plan (D9.1).

If any change or addition related to ethical issues that the project needs to take into consideration is needed, it will be included in the following deliverables of WP5 or in an updated version of the present deliverable.

6. Abbreviations

Please include any abbreviations, terms etc. used within the deliverable in alphabetical order.

Term	Definition
DEC	Websites, Patent Filings, Videos etc.
DEM	Demonstrator, Pilot, Prototype
EA	Ethics Advisor
eHMI	external HMI
GDPR	General Data Protection Regulation
HEIDI	Holistic and adaptivE Interface Design for human-technology Interactions
HMI	Human Machine Interface
iHMI	internal HMI
PU	Public
R	Document, Report
SCS	Simulated Car Sickness
SEN	Sensitive
SIS	Simulator-Induced Sickness
SS	Simulation Sickness
WP	Work Package

7. References

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[2] European Science Foundation, & All European Academies. (2011). The European code of conduct for research integrity. European Science Foundation. https://allea.org/code-of-conduct/

[3] European Union, E. (2012). Charter of Fundamental Rights of the European Union. The Review of International Affairs, 63(1147), 109-123.

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[5] de Winkel, K. N., Talsma, T. M., & Happee, R. (2022). A meta-analysis of simulator sickness as a function of simulator fidelity. Experimental Brain Research, 1-17.

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A. Annex 1 – Participant Information Sheet template

Participant Information Sheet

Research study ID	<Indicate the number of the specific study>
Study title	<Indicate the title of the study>
Location of the study	<Indicate the study location>

Thank you for your interest in our study to investigate <main objective of the study>. The study is conducted by <partner/s involved in the study>.

The following sections describe the overall approach, objectives, and methodology of the present study. After reading the present information sheet you must sign the Informed Consent to give your consent to participate in the study and to process your personal data. Do not hesitate to ask your doubts, if any before signing the consent.

1. Introduction

The European **HEIDI project**: **Holistic and adaptivE Interface Design for human-technology Interactions** (hereinafter, "**HEIDI"** or "**Project**") which is part of the topic: HORIZON-CL5-2021-D6-01-10 – Testing safe lightweight vehicles and improved safe human-technology interaction in the future traffic system, under the Grand Agreement # 101069538.

It will be conducted by a strong partnership established among 9 partners from 5 EU countries, including: one OEM (BMW), one Tier-1 supplier (MAR), two Universities (RUAS, UAH), two SMEs (TREE, NISYS) and three Research Centres (HRI-EU, VIF, VTI). Together, these partners form a core group with excellent scientific and technical interdisciplinary expertise and knowledge with researchers from different fields such as Human Factors, Computer Science, and Cognitive Modelling.

The Project

The HEIDI project aims to develop a fluid, cooperative HMI that integrates internal and external adaptive Human Machine Interface (HMI) solutions in a holistic manner. This cooperative HMI effectively synchronises driver data and data from other road users to facilitate an optimal joint action between the actors, following the foresight safety concept. With this, the HEIDI HMI solutions guarantee that all road users share the same understanding of the situation with a view to ensuring a safe interaction.

To realise this overall aim several technical innovation modules will be developed. HEIDI will develop 3 HMI solutions, namely fluid internal and external HMIs, and a cooperative HMI, demonstrated in two passenger vehicles. These new HMI solutions will be prototyped and validated in a multi-user simulation environment and in real vehicle prototypes.

The HMIs modules specifically will be:

- a driver monitoring system which detects critical driver states in real time, extended by driver behaviour prediction
- a pedestrian monitoring system which detects road user type, attentional level, and overall capability in real time, while providing the most likely future behaviours
- a situation assessment and decision model which identifies and addresses interaction partners by suggesting a safe joint behaviour based on combined sensed inputs, and
- a situation resolution and tracking module which continuously tracks whether the recommended joint actions are followed and triggers HMI countermeasures if needed.

HEIDI will develop novel AI-based (Artificial Intelligence-based) functions for identifying pedestrians' category (e.g., older adults) and ability using visual information. Furthermore, HEIDI will provide driving driver state modelling, based on existing models and extended by driver behaviour prediction algorithms, which sense based on current external context and vehicle data, what actions the driver is likely to do next.

The HMI solutions will be tested in 10+ empirical studies to tightly link design and development efforts through sufficient iterative refinement. HEIDI studies will use IT devices and/or driving simulators that will use interaction technologies such as large screens, touch screens, virtual reality technology, HMIs, etc.

The HEIDI project brings together key industry and academic partners that provide a unique infrastructure for developing, testing, and validating the proposed HMI concepts, such as the co-simulation environment provided by VTI, where pedestrians and drivers can interact in the same experiment in two interconnected simulators, and the facilities provided by RUAS, where real vehicles can interact with real pedestrians in a safe environment. Additionally, the HEIDI project will develop recommendations for regulation and standardisation guidelines to EuroNCAP and to IEEE, especially focusing on external HMIs, as this area is still characterised by high uncertainty for manufacturers.

2. Study description

<add a brief introduction about the specific study approach>

[Please provide details of models, algorithms, and IT devices used in the study]

a. Objectives

<describe the general objective and the specific objectives of the study>

b. Methodology

<describe the methodology that will be followed during the study>

[Please briefly describe the study procedure so that the participants are given a good impression of what they have to expect]

Duration of the study: […]

c. Your task

In this study you are asked to <explain in brief the study and the type of tasks participants need to carry out>. The required time is approximately xx hours.

[Description of study task(s); if required, location at which study is conducted]

Your participation in the study is voluntary and you can withdraw from the study at any time without giving reasons.

3. Data collection and measurements

<indicate the personal data that will be collected during the study and the specific measurements that will be assessed>

4. Outcomes

<describe the expected outcomes of the study>

5. Target group and conditions of participation

Test subjects must meet the following criteria to take part in this study:

- <please indicate the criteria that participants must meet>
- <…>
- <…>

6. Potential discomforts/risks

[You do not incur any risk by participating in this study. Alternatively: indicate potential discomforts/risks related to the test, environment, or IT devices used]

If any unusual measurement coming from physiological parameters or health measures (e.g., heart rate, visual acuity, etc.) is observed the principal investigator of the study will check if the participant provided consent to be informed about it. If there is any health emergency coming from this observation the principal investigator is encouraged to call emergency services and provide medical attention to the participant.

All researchers involved in the tests will ensure that nobody will be hurt when performing the experiments. If participants feel sick or present any health issue during the execution of the tests, the principal investigator should provide prompt health care and call emergency services if necessary.

7. Contact details

If you have any questions about the study or concerns about your rights as a participant, please contact the *principal investigator of the study*: <Firstname Lastname>, Tel. +xxxxxxxx, firstname.lastname@xxx.xxx.

B. Annex 2 – Informed Consent template

Informed Consent

Name	<Full participant name>
Date of birth	<YYYY-MM-DD>
Research study ID	<Indicate the number of the specific study>
Study title	<Indicate the title of the study>
Location of the study	<Indicate the study location>

Thank you for your interest in our study to investigate <main objective of the study>. The study is conducted by <partner/s involved in the study>.

Details of the objectives and methodology of the present study are described in the Participant Information Sheet provided together with this informed consent.

Your task

In this study you are asked to <explain in brief the study and the type of tasks participants need to carry out>. The required time is approximately xx hours.

Your participation in the study is voluntary and you can withdraw from the study at any time without giving reasons.

Information on the processing of personal data

Your consent forms the legal basis for the processing of your personal data. You have the right to revoke your consent to the processing of your data at any time. This does not affect processing prior to the time of your revocation. In addition, statutory retention and limitation periods must be taken into account, if applicable. Your personal data will be retained for the duration of the fulfilment of the above-mentioned purposes.

<name of the partners that will collect the data> will collect certain personal data about you, such as: name, address, telephone number, e-mail, gender, age, etc). <name of the partner> is the data controller for these data. Your personal data will be "pseudonymized". The assignment of encrypted data to your identity data is only possible with a list kept exclusively at the <partner in charge of store the data>, which is stored separately and is only accessible to individual authorized persons.

Your identity data will only be used to manage your participation in the study as well as to provide you with additional information regarding the study (e.g., results). If you agree to this, we may contact you again in the context of further research/studies.

You have the right to withdraw your consent. Such withdrawal does not affect the lawfulness of processing operations carried out prior to the withdrawal. You also have the right to request information about what data is stored and processed about you and to request rectification and erasure of personal data or to request that processing of the data be restricted. You also have the right to object to the processing of your personal data in other respects. To withdraw consent or make any request or objection relating to your personal data, please contact <partner name>, contact details are below.

You have the right to turn to the supervisory authority, the Data Protection Authority (<indicate the DPA assigned>), if you wish to lodge a complaint against the processing of your personal data. You also have the right to get in touch with the Data Protection Officer, contact details are below.

Declaration of consent

By checking “YES” in the second column of the table, you agree to the item in the specific table line. If the space is empty or checking as “NO”, you will be considered not to have consented.

	Please check “Yes” where applicable
I have been informed orally and in writing by the principal investigator about the purpose of the study, the expected effects, possible advantages and disadvantages, and possible risks, and have received answers to the questions I had.	
I have read and understood the written information distributed about the study.	
I had enough time to make my decision about participation.	
I understand that I am free to withdraw from the study at any time without giving a reason.	
I have had the opportunity to consider the information provided to me and ask questions about the study and my participation in the study.	
I was given information on whom to contact for questions or complaints about the study and my rights.	
I allow the data collected to be reused in future research projects with a similar focus and involving <partner name>. In such cases my personal data would not be identifiable in any report.	
I agree that films or still images of me and my participation may be shown in various contexts, for example in research reports and at conferences.	
I consent to <name of the partner in charge> processing my personal data in the manner described in present Informed Consent.	
I agree to participate in the study. I am voluntarily participating in the study and that I may discontinue participation at any time during the study period.	
I agree that <name of the partner> shall not be liable for any damages that may occur during the study, except for damages caused by <name of the partner> wilful misconduct or gross negligence	
I agree to be informed if any unusual measurement coming from physiological parameters or health measures (e.g., heart rate, visual acuity, etc.) is observed.	
If any side effects occur, I will contact *Researcher name* that will be in charge to contact medical services if necessary.	

Signed .....

Date: .....

Name.....

Contact details

If you have any questions about the study or concerns about your rights as a participant, please contact the *principal investigator of the study*: <Firstname Lastname>, Tel. +xxxxxxxx, firstname.lastname@xxx.xxx.

Data controller contact:

<indicate the contact of the data controller: name, address, email, tlf. etc.>

Data Protection Officer

< indicate the contact of the data protection officer: name, email, tlf. etc>

Examiner’s confirmation

I have provided the research participant with information about the study, which I believe is accurate and sufficient for the participant to fully understand the nature of the study and its risks and benefits, as well as the research participant's rights. There has been no coercion or undue influence. I have witnessed the participant signing this document.

Name of the investigator: .....

Signature: .....

Date: .....

C. Annex 3 – Guide for investigators

The following checklist is a guide for the investigators conducting a study within HEIDI's validation phase to correctly involve human participants. Please, go through this list every time you involve a new participant in your tests and validations.

1. Check if the participant complies with the target group and conditions of participation set for your specific study. These conditions should be explained in the "Participant Information Sheet" section 5.
2. Participant Information Sheet: provide to the recruited participant the "Participant Information Sheet" (Annex 1), explain the HEIDI project approach and the objectives, methodology, tasks to be completed, data management, expected outcomes and possible discomforts/risks of the specific study. Also, provide the names and contact details of the principal investigator of the study.
3. Give some time to the participant to read the "Participant Information Sheet" and then ask him/her if there is any doubt or question.
4. Informed Consent: After explaining HEIDI's approach, the information related to the specific study and solve all the doubts and questions, ask the participant to complete and sign the "Informed Consent" (Annex 2) to confirm the participation in the study, agreeing to the items detailed in the document.
5. The principal investigator must also sign the "Informed Consent", specifically the "Examiner's confirmation" section.