D9.1 Ethics Requirement No.1 - GEN

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1 GEN – Requirement No.1

1.1 Templates of informed consent sheets and information sheets

Attached to this document, you find the templates of the informed consents and information sheets from all partners conducting studies with human participants during the course of the project (see Appendix 2.1).
Throughout the project the filled-out informed consents and information sheets will be collected from all participants of all AutoMate studies and stored at the partner organizations according to the data protection requirements of the Directive 95/46/EC of the European Parliament and made available to the PO on request.

1.2 Details on incidental findings policy

Incidental findings are defined as "previously undiagnosed medical or psychiatric conditions that are discovered unintentionally and are unrelated to the current medical or psychiatric condition which is being treated or for which tests are being performed[2]".
The studies conducted in AutoMate neither involve medical nor psychopathological diagnosis. Thus, there will be no unintentionally discovered current medical or psychiatric conditions of participants in AutoMate and a policy for those findings is not applicable for this project.

1.3 Health and Safety Procedures for staff

The consortium of AutoMate will comply with the guidelines of the occupational safety and health Framework Directive 89/391/EEC "Guidance on risk assessment at work" of the European Parliament (https://osha.europa.eu/en/safety-and-health-legislation/european-guidelines).

Compliance with these principles is guaranteed as they are respected in all projects conducted in each partner organization and thus do not have to be newly introduced. Accordingly, they are already implemented and controlled procedures.

[2] https://en.wikipedia.org/wiki/Incidental_findings

As an example, at Ulm University, the necessary measures to guarantee work safety as described in these guidelines are implemented and controlled by the activities of the department for work safety. (http://www.uni-ulm.de/en/einrichtungen/administration/dezernat-5/arbeits-und-umweltschutz/arbeitssicherheit/). Besides others, these procedures involve the following:

- Consultation for questions concerning work safety, fire and explosion protection and accident prevention
- Preparation of operation instructions and risk assessments
- Provision of materials for safety instructions and briefings
- Selection and testing of personal protective equipment
- Safety inspections with registration and elimination of risks and deficiencies
- Control in handling of hazardous substances
- Organization of work security:
    - First responders
    - Voluntary firemen
    - Company doctor
    - Escape and emergency routes
    - Fire safety regulations
    - First aid posters

Similar organizational structures in all partner organizations of the AutoMate consortium guarantee compliance with health and security guidelines.

1.4 Health and safety procedures participants

In the AutoMate project all studies involving automated vehicle prototypes in real traffic use specific measures to ensure safety of study personnel and participants.

In terms of anticipated risks for participants in the studies conducted for AutoMate, the most probable risk is of psychological nature in terms of mental or emotional stress in experiments providing tasks with high cognitive demands in order to test system behaviour during driver distraction. The risk of this negative outcome is below 10% and will not have any harmful long-term consequences. To further reduce any negative consequences for the participants in this regard, informed consent will be employed along with extensive debriefing and a respectful treatment of the participants at all times.

In studies conducted with driving simulators, a physical risk to the participants is simulator sickness, which normally has a likelihood to occur in less than 1% of the cases. To reduce this risk, the partners will preselect

participants on basis of prior experience with a simulator and exclude subjects, who experienced prior episodes of simulator sickness. Furthermore, the experiments will be designed in a way to ensure that participants have enough training time to get used to the simulator setting by slowly psychologically and physically accustom themselves using the simulator.

In studies with demonstrator vehicles (real traffic scenarios to reduce any physical dangers for the participants during driving studies, all demonstrator vehicles will be built up in accordance with the local and the European laws, regulations and standards and have the registration for usage in public traffic (e.g., given by national technical service organizations such as TUEV SUED in Germany and relevant public authorities). Additionally, all possible measures will be taken to make the driving tests as safe as possible. This involves:

- All participants will be well trained security drivers, who are members of the development team of the automated test vehicles. There will be no naïve test participants.
- Training of security drivers involves a special course, in which the drivers exercise diverse situations in which the automation arrives at its limits and learn how to take over control in a safe manner
- At all times, two security drivers will be present in the vehicle during the test drives:
    - Security driver 1 as a participant and driver, who monitors the road at all time and is always ready to take over control immediately (by any action on the steering wheel or the pedals)
    - Security driver 2 as an observer of the automation status in regard to sensors, object tracking and trajectory planning
    - As soon as a problem is detected, the security driver takes over control
    - Equipment of an emergency stop switch to turn off automation

Summarising, there should not be any considerable danger for participants to be involved in any major accident due to the experimental setting of the test drives. As in everyday driving there is a small risk (<.01%) to be involved in minor accidents, which the consortium will reduce by a thorough briefing of participants and driving as much on test tracks and simulators as possible. In those experiments, where the test drives will take place on public roads, participants (being members of the AutoMate partner's development team) will be sufficiently insured against all risks.

1.5 AutoMate Ethics Board

An Ethics Board with representatives from all partners conducting studies with human participants has been established in February 2017. The following representatives assemble the AutoMate Ethics Board:

Partner	Representative	Contact
OFF	Dr. Andreas Luedtke	luedtke@offis.de
ULM	Prof. Dr. Martin Baumann	martin.baumann@uni-ulm.de
VED	Mercedes Bueno-Garcia, PhD	mercedes.bueno-garcia@vedecom.fr
DLR	David Käthner	David.Kaethner@dlr.de
CRF/REL	Elisa Fornaciari	elisa.fornaciari@re-lab.it

For each study conducted in AutoMate the responsible partner organization has to seek ethical approval. For this purpose, a screener catalogue (see Appendix 2.3) with ethical questions has to be filled out prior to any data collection for each study to indicate if the planned study concerns any critical elements or characteristics that make a formal and in-depth ethical approval procedure necessary.

If all questions are answered with "no", no formal ethical approval is necessary and the filled-out screener catalogue with all questions answered with "no" has to behanded in to the AutoMate Ethics Board. If one of the questions is answered with "yes" a formal ethical approval has to be obtained. This can either be accomplished by the AutoMate or the parent organization's Ethics Board. The workflow (3 step process) for ethical approval in AutoMate is depicted in Figure 1.

Besides the ethical approval of the project studies, the Ethics Board takes the following responsibilities in the AutoMate project:

- Monitor the ethical concerns in this project and answer ethical questions of the partners conducting studies with human participants
- Monitoring and verifying the ethical approval standards of all partners
- Providing a report, which is submitted with the financial statements

The Ethics Board will supervise and guarantee confirmation and accordance of all actions and all partners within the project to all applicable regional and EU-level Health and Safety procedures. Institutional ethical approval procedures and procedures on how to integrate institutional ethical boards for each partner are included in the Appendix (Appendix 2.3).

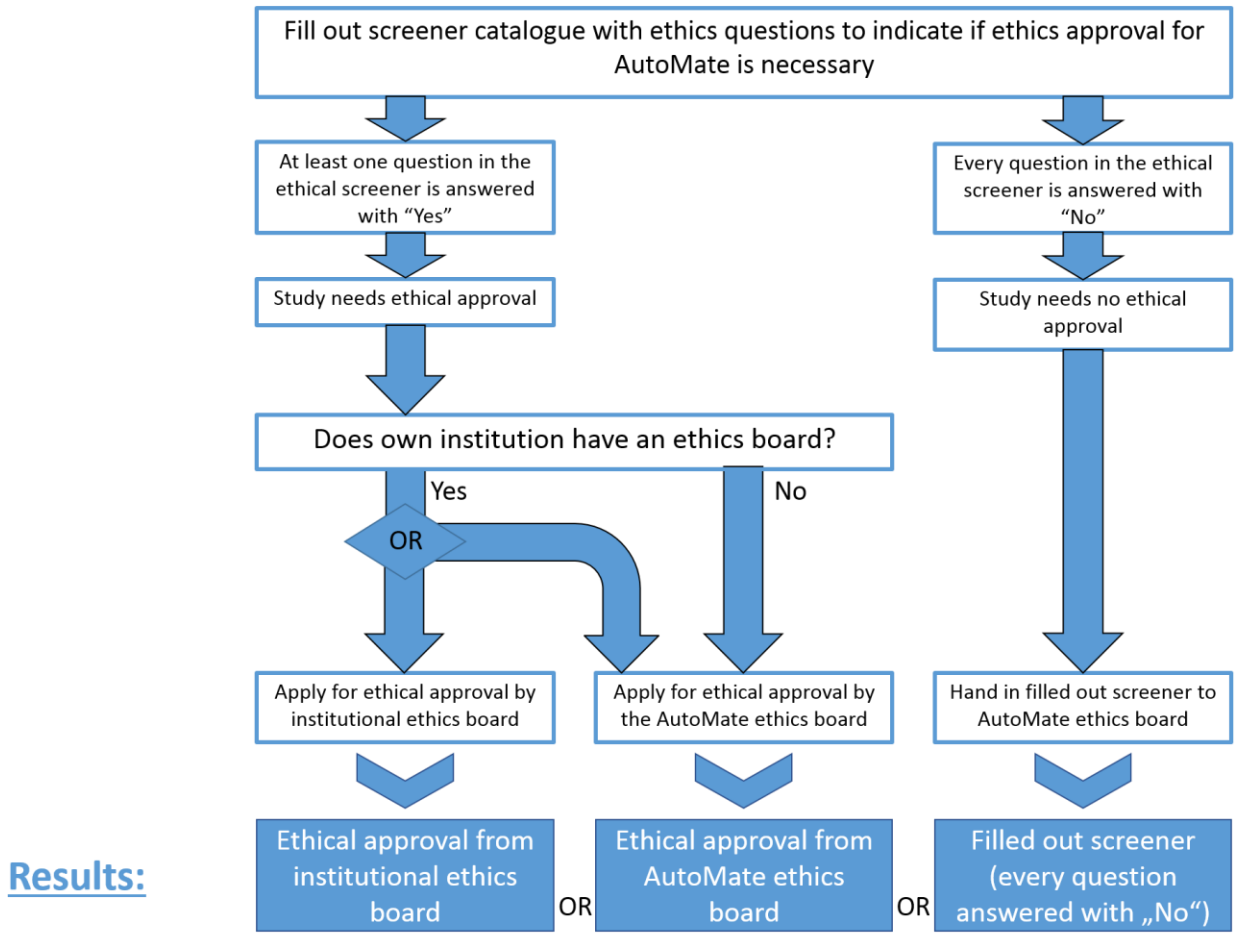

Figure 1. Workflow for ethical approval in AutoMate.

2 Appendix

2.1 Informed consent templates and/or information sheets from AutoMate partners

CAF:


Consent-CAF.docx


Information-sheet-CAF.docx

DLR:


INFORMED CONSENT.docx


PARTICIPANT INFORMATION.docx


Codeword_anonym_V2-OFFIS.docx

OFF:


informed consent.docx


safety instructions and training.docx


study description.docx


2016-08-19_TLInfo_Allg_V4_01-OFFIS.dc

REL/CRF:


Informativa_liberatoria_privacy_2016-


Informativa_liberatoria_privacy_2016.dc

ULM:


Informed Consent UULM ENG.docx


Informed Consent UULM DE.docx


Information Sheet UULM ENG.docx


Information Sheet UULM DE.docx

VED:


WP9_informed consent.docx

2.2 Ethics screener catalogue


Ethics Screener_AutoMate_

2.3 Description of institutional ethical approval procedures and of procedure on how to integrate institutional ethical boards by partners

DLR:

ETHICAL APPROVAL PROCEDURES.docx

OFF:

Ethics_Process_OFFIS.pdf

ULM:

Statement for Ethics UULM.docx

VED:

WP9_Ethics.docx

WP9_Ethical procedure_VED.doc