# D2.1 : Report on ethical framework for handling personal data, and sharing and access to data within TRUSTY

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## Abstract

This deliverable aims to specify premises for the handling of personal data, such as informed consent, conditions for privacy protection through pseudo-anonymization, and effective means for consent withdrawal, in accordance with GDPR, the former Article 29 Working Party Guidelines, relevant national legislation, and relevant international standards. The overall goal of the current D2.1 is to define a Code of Conduct that has been agreed upon by all users of collected and linked data in the consortium in order to guide the transparent and responsible re-use and sharing of consented and non-consented data (registries, spontaneous reports, research data, etc.), as GDPR establishes the limits and premises for handling personal data in Europe. Because different rules apply to different types of data, the primary task here is to define the ethical and legal requirements for collecting and bringing data into the project. The document is divided into three sections: one on good research practices that all TRUSTY project partners agreed to follow, another on data management and privacy issues, and a third on participant recruitment criteria.

## Authoring & approval

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# TRUSTY

TRUSTWORTHY INTELLIGENT SYSTEM FOR REMOTE DIGITAL TOWER

TRUSTY

This document is part of a project that has received funding from the SESAR 3 Joint Undertaking under grant agreement No 101114838 under European Union's Horizon Europe research and innovation programme.

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# 1 Good research practices to be accomplished within TRUSTY project

According to the The European Code of Conduct for Research Integrity developed by ALL European Academies (ALLEA), TRUSTY consortium highlighted and agreed to adhere to some crucial points for good research design, conduction, and dissemination, reported below.

## 1.1 Principles

Good research practices are based on some principles aimed at ensuring research integrity with respect to:

1. Reliability: concerning design, methodology, analysis, and use of resources;
2. Honesty: concerning development, review, report, and dissemination, in a transparent, fair, complete, and unbiased way;
3. Respect: toward colleagues, participants, society, ecosystems, cultural heritage, and the environment;
4. Accountability: concerning all stages of research, from idea to management to publication; for training, supervision, and mentoring; finally for the potential wider impact of the research results.

## 1.2 Good research practices

### 1.2.1 Research Environment

Research institutions and organisations support proper infrastructure for the management and protection of data and research materials in all their forms (encompassing qualitative and quantitative data, protocols, processes, other research artefacts and associated metadata) that are necessary for reproducibility, traceability, and accountability.

### 1.2.2 Training, Supervision and Mentoring

Senior researchers, research leaders and supervisors' mentor their team members and offer specific guidance and training to properly develop, design and structure their research activity and to foster a culture of research integrity.

### 1.2.3 Research Procedures

Researchers consider the state-of-the-art in developing research ideas, in addition they design, carry out, analyse, and document research in a careful and well-considered manner. Concerning research funds, researchers make of them a proper and conscientious use. Researchers publish results and interpretations of research in an open, honest, transparent, and accurate manner, and respect confidentiality of data or findings when legitimately required to do so. Researchers report their results in a way that is compatible with the standards of the discipline and, where applicable, can be verified and reproduced.

### 1.2.4 Safeguards

Researchers handle research subjects, be they human, animal, cultural, biological, environmental, or physical, with respect and care, and in accordance with legal and ethical provisions.

### 1.2.5 Data Practices and Management

Researchers, research institutions and organisations ensure appropriate stewardship and curation of all data and research materials, including unpublished ones, with secure preservation for a reasonable period.

### 1.2.6 Collaborative Working

All partners formally agree at the start of their collaboration on expectations and standards concerning research integrity, on the laws and regulations that will apply, on protection of the intellectual property of collaborators, and on procedures for handling conflicts and possible cases of misconduct.

### 1.2.7 Publication and Dissemination

Authors ensure that their work is made available to colleagues in a timely, open, transparent, and accurate manner, unless otherwise agreed, and are honest in their communication to the public and in traditional and social media.

# 2 Data Management & privacy issues

## 2.1 Ethical and legal conduct of the study

TRUSTY project is committed to the adherence to a fair ethical and legal conduct of the study. To accomplish such objective, each partner of the consortium will obtain the approval of its internal ethical committee or equivalent, previously of the performance of experimental activities. Moreover, TRUSTY project defined an internal Ethical Committee, which composition and role (roles defined in accord to[3]) include:

1. MDU: Shaibal Barua (member)
2. UNISAP: Giulia Cartocci (secretary)
3. ENAC: Christophe Hurter (chairman)
4. DeepBlue: Elizabeth Humm (member)

It is important to specify that the composition includes one member from each partner, so to equally represent all the interested parties.

Finally, for each partner it was already defined a Local Data Manager, in charge of interacting with Data Controller (D2.2).

The experimental protocols and procedures are designed to ensure respect for the guiding principles detailed in the Declaration of Helsinki of 1975 as revised in 2000, statement of ethical principles for medical research involving humans. It means that all the studies related with an experimental phase in the TRUSTY project will also be carried out in accordance with the applicable local law(s) and regulation(s) and with the strict respect of the General Data Protection Regulation (GDPR) employed in the European Union (EU).

## 2.2 Informed consent procedures

Once the verification of the requirements for the candidate participant is completed, the Principal Investigator (PI) will provide to the participant three different documents all necessary for the informed consent. Such three documents will be provided in the following specific order:

1. Detailed description of the experimental protocol and of its objectives in TRUSTY project (Information Sheet);
2. GDPR compliant information notice about the data collection, storage, and processing;
3. GDPR compliant informed consent form for participation to the experiments.

As general concept, the participant must be informed through the informed consent about experimental procedures and objective and that their personal data will be used by the investigators

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10293659/

in accordance with local data protection law. The level of disclosure of their identity must also be explained to the participant.

The participant in the experimental protocol will receive a copy of the projects and experimental protocol's descriptions together with a copy of the informed consent to be signed. The original paper format of the signed informed consent will be stored by the Principal Investigator (PI) of the local partner where experimental activities will take place (ENAC) in a secure closet, within a restricted and secured access area.

## 2.3 Templates of the informed consent and information sheet

The templates of the informed consent and information sheet, provided to the experimental participants in the TRUSTY project will be formulated point by point to include:

As Information Sheet, the following:

- Data controller presentation
- Information on data collected (bio-signals and behavioural) and kind of participation required for how much time (no more than 5 hours all included); and potential risks for participants
- Why the data collection is done
- Who is the PI and his/her collaborators
- Where the experimental phase will be carried out
- Rights of the participants to withdraw from the experiments at any time.

As GDPR compliance the following:

- Data Controller Contacts;
- Data Protection Officer (DPO) Contacts;
- Objective of data processing;
- Personnel authorized to the data processing;
- Pseudonymization and security procedures;
- Data storage procedures;
- Description of eventual data transfer to third parties within the EU;
- Art. 15-22 GDPR UE (UE/2016/2017/-GDPR;

As Covid-19 Emergency precautions

- Description of safety rules in the experimental site.

As specific to sign Consensus self-declarations of:

- Confirmation of reading the above-mentioned information;
- Participation acceptance.

## 2.4 Data handling and safety procedures

### 2.4.1 Data protection

To completely ensure security in personal data management the signed informed consent will be stored in a secure place and a randomly generated and unique identifier will be assigned to each participant by the PI. Such procedure, called pseudonymization, is a data management technique that is highly recommended by the GDPR as one of the data protection methods. Any participant related records or datasets will be then managed or transferred in all data related to the study with this identifier only. Participant names or any information which would make the participant identifiable will never be transferred. In particular, the pseudonymization procedure following the GDPR protocol, will be performed in all the sites involved in the project in a completely secure mode, in agreement and with the approval of local DPO.

### 2.4.2 Data fair management and minimization

#### 2.4.2.1 Pseudonymization process at local level

Each raw data collected during the TRUSTY project from the same subject will be associated to a unique alpha-numeric identifier. The per-user data resulting from the analyses and processing performed by each partner must be labelled with a unique and randomly chosen identifier specific for the user at hand. It means that data results are not associated with user's identity: starting from the raw data, the partners will process the data and extract high level information.

The name of the research participant will appear only on the consent forms that will be strictly secured by the PI following the internal security rules of the Data Controller.

Information of the association between the code and the participant's identity will be stored in a specific Excel file, owned by each Data Controller, representing each partner involved in the data collection. The Excel sheet is secured through 256-bit AES (Advanced Encryption Security) codification and password. The Data Controller is responsible for the Excel sheet security. Participant's data are stored by the local centre responsible for the data collection, following the European and National legal requirements.

The raw data collected during the TRUSTY project will be encrypted by the partner who collected them.

#### 2.4.2.2 Pseudonymized data storage

Personal data procedures in the testing facilities provided by: ENAC, DBL and UNISAP will be in direct contact with the users that will perform the different studies of the TRUSTY system. To accomplish all legislative requirements, these organizations will nominate a Data Processor who will work together with the Data Controller. Data processors process data on behalf of Data controllers because of a relationship that links them. The Data processor's scope for action will be limited by the service they will provide to the Data controller. Data processors will be responsible for contacting with the test subjects to provide the information sheet for the TRUSTY project and obtain consent from them.

As a general policy the correspondence between the participant's code and the participant's identity will be held in a suitably encrypted table held on a secure computer at the Data Controller's premises. No reference about the participant's code will be written on the respective consent form. All data in the data storage platform will be then pseudonymized by assigning a user code to each participant.

All research data produced during TRUSTY will be stored in dedicated hard drive. All the partners will transfer among them for the project purpose only pseudonymized data. Each transfer will be protected by end-to-end encryption. The software used for the encryption and decryption procedure will be GnuPG.

It means that in the project Data management plan information of the association between platform user and participant of each experimental location is stored by Local Data Manager in Excel format and with the specific data. The Excel sheet is secured through 256-bit AES codification and password. The Data Controller is responsible for the Excel sheet security. All shared reports, results, internal communications, and external publications do not contain any personal data of the participant.

## 2.5 Ethics risks related to the data processing.

The ethics approval will be requested to the Institutional Committee in charge at ENAC or equivalent.

The project will consider and comply all the different international regulations related to the acquisition and use of human physiological data, in particular:

- the Declaration of Helsinki (*World Medical Association*, 1964, last revision in 2013[4]), statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data;
- the Belmont Report (*National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research*), 1979[5]), summarizing ethical principles and guidelines for research involving human subjects.

No unethical use of the data will be allowed during the project development.

## 2.6 Ethical issues related to AI system while using by human

TRUSTY project activities complied with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards

[4] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[5] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

- applicable international, EU and national law (in particular, the principles and values enshrined in the EU Charter of Fundamental rights and the EU Treaties).

In accordance with the Ethics Guidelines for trustworthy AI[6] all the activities developed within TRUSTY project are characterized by an AI that is:

(1) lawful - respecting all applicable laws and regulations

(2) ethical - respecting ethical principles and values

(3) robust - both from a technical perspective while considering its social environment

Furthermore, the just mentioned Guidelines put forward a set of 7 key requirements that AI systems should meet to be deemed trustworthy. A specific assessment list aims to help verify the application of each of the key requirements that we considered during the development of TRUSTY:

1. Human agency and oversight: AI systems should empower human beings, allowing them to make informed decisions and fostering their fundamental rights. At the same time, proper oversight mechanisms need to be ensured, which has being achieved in TRUSTY through a human-in-the-loop approach
2. Technical Robustness and safety: AI systems need to be resilient and secure. They need to be safe, ensuring a fallback plan in case something goes wrong, as well as being accurate, reliable, and reproducible. That is the only way to ensure that also unintentional harm can be minimized and prevented.
3. Privacy and data governance: besides ensuring full respect for privacy and data protection, adequate data governance mechanisms must also be ensured, considering the quality and integrity of the data, and ensuring legitimised access to data.
4. Transparency: the data, system and AI business models should be transparent. Traceability mechanisms can help achieving this. Moreover, AI systems and their decisions should be explained in a manner adapted to the stakeholder concerned. Humans need to be aware that they are interacting with an AI system and must be informed of the system's capabilities and limitations.
5. Diversity, non-discrimination, and fairness: Unfair bias must be avoided, as it could have multiple negative implications, from the marginalization of vulnerable groups to the exacerbation of prejudice and discrimination. Fostering diversity, AI systems should be accessible to all, regardless of any disability, and involve relevant stakeholders throughout their entire life circle.
6. Societal and environmental well-being: AI systems should benefit all human beings, including future generations. It must hence be ensured that they are sustainable and environmentally friendly. Moreover, they should consider the environment, including other living beings, and their social and societal impact should be carefully considered.
7. Accountability: Mechanisms should be put in place to ensure responsibility and accountability for AI systems and their outcomes.

[6] https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

Auditability, which enables the assessment of algorithms, data and design processes plays a key role therein, especially in critical applications. Moreover, adequate an accessible redress should be ensured.

TRUSTY project performed and is currently monitoring during its development the Ethics issues checklist reported at the 8.3 paragraph of the Guidance "How to complete your ethics self-assessment"[7] to assess risks relative to AI employment, also consulting the Assessment List for Trustworthy Artificial Intelligence (ALTAI)[8], which results are below reported:

ALTAI's self-assessment results:

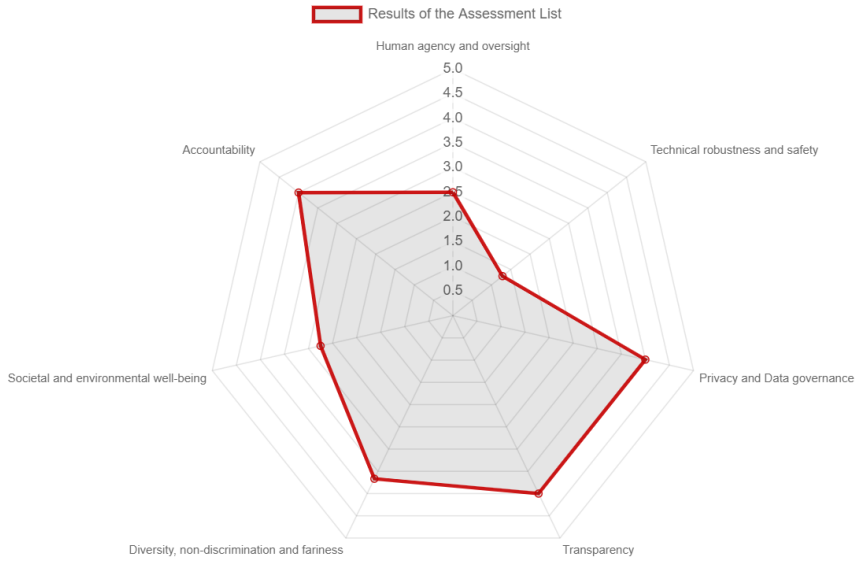


Fig.1 ALTAI tool self-assessment results for TRUSTY project.

ALTAI's Recommendations:

- Human agency and oversight

  Put in place any procedure to avoid that the system inadvertently affects human autonomy.

  Give specific training to humans (human-in-the-loop, human-on-the-loop, human-in-command) on how to exercise oversight.

[7]https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

[8]https://futurium.ec.europa.eu/en/european-ai-alliance/pages/welcome-altai-portal#:~:text=The%20Assessment%20List%20for%20Trustworthy%20Artificial%20Intelligence%20%28ALTAI%29%2C,the%20trustworthiness%20of%20their%20AI%20systems%20under%20development

- Technical robustness and safety

  No recommendation for this requirement.

- Privacy and Data Governance

  No recommendation for this requirement.

- Transparency

  No recommendation for this requirement.

- Diversity, non-discrimination and fairness

  Test for specific target groups or problematic use cases.

  Assess and put in place processes to test and monitor for potential biases during the entire lifecycle of the AI system (e.g. biases due to possible limitations stemming from the composition of the used data sets (lack of diversity, non-representativeness).

  Put in place educational and awareness initiatives to help AI designers and AI developers be more aware of the possible bias they can inject in designing and developing the AI system.

  Consult with the impacted communities about the correct definition of fairness, such as representatives of elderly persons or persons with disabilities.

  You should ensure that the AI system corresponds to the variety of preferences and abilities in society.

  You should assess whether the AI system's user interface is usable by those with special needs or disabilities or those at risk of exclusion.

  You should ensure that Universal Design principles are considered during every step of the planning and development process, if applicable.

  You should take the impact of the AI system on the potential end-users and/or subjects into account.

- Societal and environmental well-being

  Consider the potential positive and negative impacts of your AI system on the environment and establish mechanisms to evaluate this impact.

  Define measures to reduce the environmental impact of your AI system’s lifecycle and participate in competitions for the development of AI solutions that tackle this problem.

  Provide training opportunities and materials for re- and up-skilling measures.

- Accountability

  To foresee 3rd party auditing or guidance can help with both, qualitative and quantitative risk analysis. In addition, it can contribute to generate trust in the technology and the product itself.

Given the Proof-of-Concept purpose of TRUSTY project, we do not feel all the ALTAI's suggestions as applicable. We will implement the suggestions provided through ALTAI's results in further developments of TRUSTY outcomes. In fact, future research will aim to reach higher TRL levels, and in that context the accomplishment of ALTAI's recommendations will be fully appropriate and addressed.

# 3 Participants recruiting criteria

## 3.1 Inclusion criteria

All participants will have to meet all the following inclusion criteria to be enrolled in the study:

- Healthy male and female volunteers from an age range from 18 up to 70 years (inclusive).
- Participant can understand the study instructions and provide a personally signed and dated informed consent to participate in the trial indicating willingness to adhere to all trial procedures.
- Participant admitted to this study is oriented to person, place and time and can communicate with the study staff.
- Participant is, in the opinion of the study staff, motivated to participate and to complete the study as instructed.
- Participant is willing to attend the experimental protocol in a well-rested state.
- Specific professional/personal skills, depending on each investigated application context.

## 3.2 Exclusion criteria

Participants must not meet any of the following exclusion criteria:

- Participant who currently suffers from physical diseases connected to symptomatology COVID19, including runny nose, headache, cough, sore throat, fever (defined as body temperature superior to 36.9 °C).
- Subjects who did not sign the informed consent form.

The participants of the experiments will be managed by ENAC. They will either be experts in ATM domain, ATCs, or ATC students. Any additional expert participants, if necessary, will be agreed upon by all stakeholders in TRUSTY projects and chosen once an agreement is reached. The experiments will be performed at ENAC simulators platform facilities.

## 3.3 Recruitment criteria

When the participation to the experimental protocol will be promoted by ENAC, in the advertisement will be specified that candidate participants must not meet the following items because of possible interference with data collection, therefore are not encouraged to propose themselves for participation:

- Participant who currently suffers from neurological or mental diseases or with history of these diseases (e.g., depression, anxiety, sleepiness disorders, hemicrania, etc.) during the past six months.
- Participant who assumes or have assumed in the prior six months psychoactive drugs.

## 3.4 Lifestyle / dietary restrictions

There are no lifestyle or dietary restrictions to be involved in the experimental protocols of the TRUSTY project.

## 3.5 Subject discontinuation / withdrawal from the experimental protocols

A participant may withdraw from the study at any time at their own request or may be withdrawn at any time at the discretion of the investigator for safety, behavioural compliance and he will be informed about his right clearly in the Informed Consent.