D1.3 Ethics requirements

MULTICARE

Funded by
the European Union

D1.3 Ethics requirements

Dissemination Level:	Sensitive
Lead Partner:	TU Delft
Due date:	31 March 2024
Actual submission date:	31 March 2024

PUBLISHED IN THE FRAMEWORK OF
MULTICARE (Horizon Europe grant 101123467)

AUTHORS
Alessandra Luna-Navarro, TU Delft
Azarakhsh Rafiee, TU Delft
Marc Boonstra, TU Delft

REVISION AND HISTORY CHART

VERSION	DATE	EDITORS	COMMENT
V0.1	31 January 2024	Marc Boonstra (TU Delft)	First Draft
V0.2	05 March 2024	Alessandra Luna-Navarro (TU Delft)	Second Draft
V0.3	10 March 2024	Azarakhsh Rafiee (TU Delft)	Third Draft
V0.4	15 March 2024	Simona Bianchi (TU Delft)	First Review
V0.5	26 March 2024	Łukasz Wilczyński (ASM)	Second Review
V1.0	26 March 2024	Simona Bianchi (TU Delft)	Final Version

DISCLAIMER

The information in this document is subject to change without notice. Company or product names mentioned in this document may be trademarks or registered trademarks of their respective companies.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

Table of contents

LIST OF TABLES

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

GLOSSARY

ACRONYM	FULL NAME
AI	Artificial Intelligence
CA	Consortium Agreement
DMP	Data Management Plan
DPO	Data Protection Officer
DPIA	Data Protection Impact Assessment
GA	Grant Agreement
GDPR	General Data Protection Regulation

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

1. Introduction

1.1. MULTICARE

The built environment is ill-prepared for more frequent and increasingly intense climate-related extreme events. The current building stock is particularly vulnerable because it has limited or no capacity to adapt and recover from extreme events thereby leading to building failures that cause severe socio-economic losses and adversely affecting the health and wellbeing of people. Recent scientific and technological advances in the construction industry provide timely solutions for improving the resilience for specific single hazards (e.g. flood hazard or seismic hazard), but they are often not cost effective, rarely eco-friendly and nearly never address the multiple hazards present in many locations. This is hardly surprising because there is neither a clearly defined framework for quantifying the whole-life socio-economic-environmental impacts of extreme natural events nor tools for assessing the holistic climate resilience of buildings. Consequently, it is currently very challenging to develop/select optimal solutions for real-world multi-hazard scenarios.

MULTICARE will address this challenge directly by developing new multi-criteria decision-support frameworks and providing plug & play technological and digital solutions for improving the resilience of the built environment in a cost-effective, reliable and sustainable manner. The technological solutions consist of multi-functional low-carbon resilient technologies embedded in modular and prefabricated construction for the next generation of high performance and smart buildings, characterized by enhanced safety, energy efficiency, environmental-sustainability, improved quality of life, circularity, and scalability for a broad range of natural events and end-user. The plug & play technologies will be applied to either new multi-story buildings or existing structures by means of low-invasive external interventions. The digital solutions consist of a suite of multi-disciplinary digital services and tools for performing multi-hazard resilience assessment, design, operation and management across multiple scales (material, component, building, neighborhood/city). The new digital tools will enable stakeholders to make informed decisions in the selection of materials/solutions, including for heritage buildings, and support resilient supply chains. The effectiveness of the MULTICARE solutions will be demonstrated through large-scale pilots (3 buildings, 4 neighborhoods/district) in three different European countries carefully selected for their diverse local environmental, social and economic conditions (Italy, Netherlands, Romania). Banks and institutional investors will be engaged to better understand the financial risk reduction value of resilience and update existing and future “green finance” mechanisms that will help to leverage the project results. A user-center, inclusive and participatory approach will be consistently implemented throughout the project to engage citizens and extend the durability of MULTICARE impact.

To achieve these ambitious goals, MULTICARE brings together a unique interdisciplinary Consortium of 21 partners (**Table 1.** ConsortiumTable 1. Consortium**)** from 6 different EU countries with strong R&D and practical expertise, who are either established leaders in their sector or agile SMEs in emerging fields. Altogether the Consortium members span

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

across the whole technical and value chain required for developing and implementing solutions in terms of design, digitization, manufacturing, construction and monitoring of resilient and sustainable buildings. The Consortium also includes partners with experience in social sciences, user engagement, and training to ensure the success and widespread application of new technologies in local communities. The Consortium will also support clustering activities with other relevant research projects to share knowledge and raise public awareness of building resilience. An international outreach and cooperation strategy will also be implemented to tackle the project challenges.

Table 1. Consortium

Number	Role	Short Name	Legal Name	Country
1	CO	TU Delft	TECHNISCHE UNIVERSITEIT DELFT	NL
2	BEN	PFE	PRIEDEMANN FASSADENBERATUNG GMBH	DE
3	BEN	IES R&D	IES R&D	IE
4	BEN	INCDFP	INSTITUTUL NATIONAL DE CERCETARE-DEZVOLTARE PENTRU FIZICA PAMANTULUI	RO
5	BEN	UNIROMA1	UNIVERSITA DEGLI STUDI DI ROMA LA SAPIENZA	IT
6	BEN	XLD	X-LAM DOLOMITI SRL	IT
7	BEN	STRESS	SVILUPPO TECNOLOGIE E RICERCA PER L'EDILIZIA SISMICAMENTE SICURA ED ECOSOSTENIBILE SCARL	IT
7.1	AE	UNINA	UNIVERSITA DEGLI STUDI DI NAPOLI FEDERICO II	IT
8	BEN	AMS Institute	STICHTING AMSTERDAM INSTITUTE FORADVANCED METROPOLITAN SOLUTIONS(AMS)	NL
9	BEN	PMB	MUNICIPIUL BUCURESTI	RO
10	BEN	ASM	ASM - CENTRUM BADAN I ANALIZ RYNKUSPOLKA Z OGRANICZONA ODPOWIEDZIALNOSCIA	PL
11	BEN	RoGBC	ASOCIATIA ROMANIA GREEN BUILDING COUNCIL	RO
12	BEN	RINA-C	RINA CONSULTING SPA	IT
13	BEN	UTBV	UNIVERSITATEA TRANSILVANIA DIN BRASOV	RO
14	BEN	ACER	AGENZIA CAMPANA PER L EDILIZIA RESIDENZIALE	IT
15	BEN	Boom	BOOM BUILDS B.V.	NL
16	BEN	OMRT	OMRT BV	NL
17	BEN	ROTHO BLAAS SRL	ROTHO BLAAS SRL	IT
18	BEN	ARUP	ARUP BV	NL
19	BEN	Tecuci	MUNICIPIUL TECUCI	RO
20	BEN	Hölscher	DIPL.-ING. HPLSCHER GMBH & CO.KG	DE

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

1.2. Ethics Requirements

This deliverable outlines the ethics requirements, ensuring compliance with ethical guidelines and principles throughout the project. It highlights the relevant frameworks, regulations and procedures for safeguarding human rights, privacy, and data security.

The Ethics Self-Assessment provided the following insights.

- **Ethical dimension of the objectives, methodology and likely impact**

The potential ethical issues of MULTICARE relate to collecting and processing personal data from the occupants in the demo buildings and sites to assess the baseline conditions of indoor environmental quality, safety awareness, perceived levels or risks, psychological resilience, acceptance of new technologies, aesthetics and personal preferences of the proposed designs and technological solutions. This will include monitoring in anonymous manner occupant behavior in buildings and sites. In addition, MULTICARE will use AI to develop smart predictive algorithm that can inform better early warning systems by analyzing the monitored data in aggregated manner and identify patterns of risk to climate hazards.

The following principles will be followed to ensure these issues are compliant with the relevant regulations in Ethics.

- **Use of Artificial Intelligence**

The main risk that can raise from using AI methods relates to potential gender, racial and age bias or bias against vulnerable people (such as people with disabilities and from socially disadvantageous backgrounds or minorities). To ensure the trustworthiness of the AI systems, the algorithms will be assess versus bias, non-discrimination and intersectionality. This would mean to consider methods to make sure datasets are balances in terms of diversity and that AI systems are reliable, traceable and explainable. This aspect will also be considered in the consortium seminars and training events.

- **Involvement of human volunteers non from medical studies**

Research involving human volunteers will only be considered after: (i) ethical approval will be granted by the competent office; (ii) explicit informed consent for participation in project activities following the Ethical procedures in place in each institutions and relevant EU regulations. The informed consent will include information on all the relevant aspects of the activity and associated risks and hand signature of the participants. All the data will be handled as mandated by relevant EU regulations and following GDPR regulations and the information here below provided on "Processing of personal data".

- **Processing of Personal Data**

Each partner will designate a DPO when processing personal data or the coordinator will establish a common Data Protection framework, which will be commonly agreed. All the project partners will also make sure that local official guidelines which are based on national guidelines and legislation related to environmental protection, occupational health aspects, and waste management of all materials during the entire project lifecycle will be followed. This will be appropriate included in the DMP that each partners and the whole consortium will put in place.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

- **Compliance with ethical principles and relevant legislations**

MULTICARE will comply with all pertinent ethical standards, Horizon Europe guidelines and relevant national and EU legislation including the following:

(1) Horizon Europe Rules of Participation which include ethical guidelines in Article 19 (Ethics)- The General Data Protection Regulation EU 2016/679 (GDPR) superseding the Data Protection Directive 95/46/EC;
(2) Directive 2002/58/EC, concerning the processing of personal data and the protection of privacy in the electronic communications sector, as modified by Directive 2009/136/EC. All national data protection and privacy laws for pilot countries will be also followed
(3) The Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain union legislative acts.
(4) The Horizon Europe Model Grant Agreement rules on ethical issues in Article 14 (Ethics) and Annex 5 (gender equality)
(5) The social responsibility principle, as outlined in the SATORI CEN Workshop Agreement 17145 (2017)
(6) Responsible Research and Innovation (RRI) principles, including diversity and inclusion, anticipation and reflection, openness and transparency, responsiveness and open access to scientific knowledge
(7) The European Convention on Human Rights (ECHR), especially Article 8 on the right to privacy.
(8) The Charter of Fundamental Rights of the European Union, especially Articles 7 and 8 on the rights to personal data protection and privacy
(9) National legislation and other data protection related regulations applicable to MULTICARE partners.

If necessary, the MULTICARE partners will request a permission from their National Data Protection Authorities.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

2. Use of Artificial Intelligence

2.1 Objective and Scope

This section outlines a set of ethics requirements to ensure the responsible use of AI, covering transparency, fairness, privacy, security, social impact and continuous improvement.

2.2. Transparency and Accountability

- Explainability and Transparency: AI tasks in MULTICARE project will provide clear explanations of their decision-making processes to foster trust and understanding among users and stakeholders.
- Accountability for AI Decisions: MULTICARE project will develop mechanisms for assigning responsibility when AI systems make significant decisions to be accountable for the impact of their AI applications, considering both intended and unintended consequences.

2.3. Fairness and Bias

- Avoidance of Discrimination: AI tasks in MULTICARE project actively work to identify and eliminate biases in AI systems throughout the development lifecycle.
- Diversity in AI Development: MULTICARE project will promote diversity and inclusion within AI development teams to mitigate the risk of biased algorithms, so that diverse perspectives contribute to the creation of more equitable AI systems that cater to a broader range of users.

2.4. Privacy and Security

- Data Privacy: MULTICARE project prioritizes user privacy by implementing robust data protection measures. Compliance with relevant data protection regulations and obtaining explicit consent for the collection and use of personal information will be ensured.
- Security Protocols: MULTICARE project will Implement rigorous security measures to safeguard AI systems against malicious attacks and unauthorized access. It will conduct regular security audits to identify vulnerabilities and address potential threats.

2.5. Social Impact and Responsibility

- Human-Centric Design: MULTICARE project prioritizes the well-being of individuals and communities in AI design. It considers the social impact of AI applications and prioritizes the solutions that enhance human welfare.
- Societal Benefit: MULTICARE project will develop AI technologies that contribute positively to society. It avoids creating AI systems that could be used to exploit individuals, manipulate public opinion, or facilitate harmful activities.

2.6. Continuous Monitoring and Improvement

- Ongoing Evaluation: MULTICARE project will establish processes for continuous monitoring and evaluation of AI systems in real-world scenarios. It will regularly update

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

algorithms to improve performance, address biases, and adapt to changing ethical standards.

- Stakeholder Engagement: MULTICARE project will engage with a diverse group of stakeholders, including users, experts, and affected communities. It will request feedback to enhance the ethical robustness of AI systems and address concerns raised by various stakeholders.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

3. Involvement of human volunteers non from medical studies

3.1 Objective and Scope

The primary goal of this chapter is to provide an explanation and definition of how to address ethical concerns associated with the involvement of human participants in the project. It specifically focuses on volunteers participating in non-medical studies.

3.2 Ethical Principles

During the study, the MULTICARE project will be complying with the following ethical principles towards the human beings involved that are not part of the staff of the participants:

- Respect for persons and for human dignity;
- Inform the participants of the risks and benefits of their involvement;
- Entirely voluntary participation of the participants;
- Provide a project-specific informed consent form and an information sheets;
- Be sure that the participants have fully understood the information provided in the sheets. The information sheet and informed consent form will be firstly provided in English language, however it will be translated if people do not understand English.
- Respect participants privacy;
- Protect the data, keep them as confidential and anonymized;
- Right to withdraw from the study their participation and data at any time;
- Ensuring the protection of participants from harm and discomfort;
- Explain the benefits of the project outcomes for the society.

3.3 Humans involved in MULTICARE

There will be various activities in which participants will be involved in MULTICARE Project, with the principal ones being described in the following subparagraphs. The research participants' will be provided the following two documents in order to guarantee the respect of the ethics requirements:

- An **information sheet**, which will contain sufficiently detailed information on the purposes of the analysis, so that they can make an informed, voluntary, and rational decision to participate. The report concludes with a general template for an information sheet, which will be customized by the consortium partners based on their specific activities' requirements (See "Annex 1 – Information Sheet General Template");
- An **informed consent form** to be signed by the participants. An informed consent general template (See "Annex 2 – Informed Consent General Template") will be generated to encompass all project activities involving research participation.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

Subsequently, this form will be tailored as per the specific requirements of individual consortium partners who must utilize it, but all the following elements will be contained according to the document "How to complete your ethics self-assessment":

- Written in a language and in terms they can fully understand;
- Describe the aims, methods and implications of the project activity, the nature of the participation and any benefits, risks or discomfort that might ensue;
- Explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples, or data at any time — without any consequences;
- State how data will be collected, protected during the project and whether they will be destroyed or reused afterwards;

The informed consent form is not required if national law provides for an exception (e.g., in the public interest). All the informed consent forms signed by the participants will be collected, saved in the project repository, and provided on request.

As an output of the various project activities, the acquisition and processing of personal data of the research participants' will occur, which is subject to regulation by the GDPR.

The consortium is committed to taking the necessary steps **to prevent**:

- Unauthorized collection of data without explicit informed consent from individuals under observation.
- Misuse or sale of collected data for purposes other than the project.
- Collection of data that is not strictly required to accomplish the current study. A data minimization policy and anonymization will be implemented at all levels of the project and overseen by the ethical/privacy component.

Partners are not bound to use the general templates provided in this deliverable, as long as their own templates for the different activities are in compliance with EU/National Laws. It will be evaluated in the finalization phase of the data management plan if copies of ethical approvals are required by law. Further details about data collection, protection and management will be given in the Chapter "Personal Data" of this report as also in the complementary deliverable D7.3 "Data Management Plan".

3.4 Interviews and workshops

The impact assessment focuses on key Social Key Performance Indicators. These indicators revolves around the following topics: perception of resilience, environmental comfort and health, satisfaction with design solutions. These KPIs will be quantified through workshops and interviews on site. The researcher authorised for processing human data will conduct interviews and workshops to capture the need of the essential building user groups (end users, demo-sites occupants, operators, energy manager, facility manager, owners) with regards to these aspects above-mentioned.

The interviews and workshops will be conducted by TUD in collaboration with AMS. The data collected from these interviews and workshops will be then collected and

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

translated into technical requirements for the digital and physical solution of MULTICARE, but also to assess the impact of MULTICARE intervention on social aspects. All data referring to user groups participating in the data collection campaigns, pilots and other project activities (e.g., interviews, surveys, workshops, etc.) will be managed according to specific terms that will be specified in the DMP, protecting the data subjects' rights and freedoms in relation to the processing of their personal data.

Prior to the commencement of the interview and the monitoring in the demo sites, the informed consent form will be duly signed by the interviewee and participants. Explicit consent will be requested either verbally or signed in hard copy or in digital copy..

To establish effective communication with the interviewees and participants, it is crucial to furnish them with the subsequent details, through the two documents previously described:

- The study's objective;
- The consent to record the interview and information pertaining to subsequent analytical procedures such as transcription, along with the interviewee's consent on the transcript or protocol;
- A guarantee that all shared information and data will be treated confidentially, without divulging any content that could identify the respondent;
- A concise statement clarifying the voluntary nature of participation in the interview and the interviewee's right to refrain from answering any questions.
- How data will be collected, processed, and protected.

3.5 Survey of demo site buildings for impact assessment

Surveys, questionnaires and monitoring of the existing buildings at the demo site location will be conducted throughout the duration of the project among partners, stakeholders, and end users. For the online surveys, GDPR compliant tool, such as "Qualtrics" will be used. The participants in the surveys will receive both an information sheet containing all the information related to the activity and an informed consent form to be signed for participation. All the data collected during the monitoring will be explained to the participants and treated to avoid any personal identification. When it will be no possible to prevent identification or collection of personal data, these data will be securely stored in protected databased and project drive at TU Delft, only accessible by authorised researchers. As soon as possible the data will be then anonymised. The results will then be shared only in aggregated and anonymised manner.

Similarly to the interviewees and participants, it is crucial to provide participants with the subsequent details, through the two documents previously described:

- The study's objective;
- The consent to record the interview and information pertaining to subsequent analytical procedures such as transcription, along with the interviewee's consent on the transcript or protocol;
- A guarantee that all shared information and data will be treated confidentially, without divulging any content that could identify the respondent;
- A concise statement clarifying the voluntary nature of participation in the interview

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

and the interviewee's right to refrain from answering any questions.

- How data will be collected, processed, and protected.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

4. Processing of Personal Data

Personal data may be collected and processed during the assessment of the social indicator for the impact assessment of MULTICARE. As much as possible, collection of personal data will be avoided, but in few occasions information on participants (name and contact details) may be necessary for administrative reasons. This data will be treated confidentially and never shared outside of the authorized research team. In addition, the personal data will be stored in secured database at TU Delft. Previous any collection of personal data, participants will be informed and asked for consent.

The two contractual documents that must be referenced when dealing with personal data are the GA and the CA.

The MULTICARE project will be complying with the following main obligations towards the treatment of personal data obtained as output from different project activities from the research participants' according to the document "How to complete your ethics self-assessment":

- Appropriate safeguards of the data;
- Anonymisation or pseudonymisation of the data to be processed;
- Free and fully informed consent of the persons concerned of their data processing;
- Inform the research participants' that their data will be treated and let them know their rights and potential risks related to the data processing;
    - Inform the research participants' of the data processing operations and provide the contact details of the DPO (Art 13/ Art 14 GDPR);
- Application of "Data Minimisation Principle";
- Higher safeguards for data processing operation that can raise a higher ethical risks;
- DPO must be consulted for complex, sensitive, or large-scale processing or data transfers outside of the EU;
- Data will be protected and secured in appropriate way to their risks;
- Responsible for the data collected and processed.

As an overarching principle, each partner assumes the role of an independent data controller and bears exclusive responsibility for their activities involving the processing of personal data.

During the project, all personal data that is collected will be treated with the highest level of confidentiality and security. Measures will be taken to ensure that unauthorized individuals will not have access to the data at any point during the research. Precisely the following procedures will take place:

- **Information Sheet**: All participants will receive an information sheet briefly describing the project and his goals; including information of collection and treatment of personal data;
- **Informed Consent Form**: All participants will receive clear and comprehensive informed consent form regarding any monitoring and data acquisition processes and will have the opportunity to provide their consent. It is emphasized that all individuals involved in the study will be strictly volunteers, and prior to participating, they will receive detailed oral information explaining the procedures and their

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

involvement;

- **Anonymization**: To ensure the privacy of participants, all collected data will undergo a process of anonymization, encryption, and storage in secure files. Alternatively, suitable pseudonymization methods will be employed to ensure the anonymity of the data; In instances where feasible, real names will be substituted with nicknames..
- **Secure Storage**: Personal data protection will be effectively safeguarded through the implementation of secure procedures and appropriate technologies. Computer and/or could based solutions where data are stored are secured with the passwords.
- **Limited Access**: Access to these files will be limited to authorized staff members only;
- **Data Sharing**: Any sharing or transfer of data will be conducted in strict adherence to privacy protocols and legal requirements. Data will only be shared with authorized individuals or entities for research purposes, ensuring that proper data protection measures are in place and compliance with relevant regulations is upheld.
- **Data Retention**: Personal data will be retained and utilized for a period of up to five years following the last project payment or until consent is withdrawn, whichever occurs sooner. Once this timeframe is reached, all personal data will be securely deleted from the consortium's databases using appropriate software and/or hardware procedures that prevent unauthorized recovery (e.g., DiskWipe).
- **Data Minimisation Policy**: Collect only strictly necessary data to accomplish the project goals.
- **Development of a DMP**: The deliverables issued for data management during the project will detail all the information regarding the above aspects..

These procedures will guarantee the confidentiality and privacy of the participants' data, complying with ethical principles, EU regulations. It will be evaluated in the finalization phase of the requirements for the data management plan if the DPIA is required.

The DPO will be actively involved in all project phases and aspects that pertain to privacy and data protection concerns. This comprehensive involvement will guarantee complete adherence to privacy and data protection regulations.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

5. Conclusion

This deliverable outlines the ethics requirements to ensure compliance with ethical guidelines and principles throughout the MULTICARE project, particularly focusing on safeguarding human rights, privacy and data security.

Potential ethical issues in the project entails collecting and processing personal data from occupants for assessing indoor environmental quality, safety awareness and psychological resilience. This are also related to the use of AI for predictive algorithms, emphasizing the importance of addressing biases and ensuring reliability and transparency. Involvement of human volunteers requires ethical approval and explicit informed consent, following relevant regulations. Data protection measures include designating a DPO and complying with GDPR regulations. The deliverable emphasizes the importance of adhering to local guidelines and legislation regarding environmental protection and occupational health throughout the project lifecycle.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

Appendix I

HUMAN RESEARCH ETHICS INFORMED CONSENT TEMPLATES AND GUIDE

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

Delft University of Technology
HUMAN RESEARCH ETHICS
INFORMED CONSENT TEMPLATES AND GUIDE

The following templates have been developed by the Human Research Ethics Committee (HREC) to assist you in the design of your Informed Consent materials for non-medical research involving human Research Subjects. **It is important to adapt this template to the outline and requirements of your particular study, using the notes and suggestions provided.**

For additional information or specific expertise on preparing your Informed Consent materials you can consult the following:

- The TU Delft Research Ethics webpages,
- Your faculty Data Steward, the TU Delft Privacy Team
- Our brief guide on Completing the HREC checklist
- Our Risk-Planning tool, Managing Risk in Human Research

If you have any questions about applying for HREC approval which are not dealt with on the Research Ethics webpages, please contact HREC@tudelft.nl

You can find **Dutch versions** of the Informed Consent templates in the Informed Consent section of the Research Ethics webpages.

Informed Consent as a legal and ethical agreement

The key function of the Informed Consent (IC) process is that this is where you (the Responsible Researcher) come to an agreement with your participants about what they will do for your research and what you will do, both legally and ethically, to ensure their physical, emotional and reputational security. It is key that they know exactly what – and particularly what potential risks – they are agreeing to, and that this is clear in your agreement, and executed in practice.

Two types of Informed Consent

"Informed Consent" covers two distinct, if overlapping, elements of a participant's agreement to participate in scientific research. These are essentially: consent to participate in the research and consent to the way in which any personal data will be processed and managed.

- **Research Participation** – obtaining a participant's consent to participate is essential for any research involving human "subjects". It requires researchers to flag the potential physical, emotional or other risks they might be exposed do by virtue of the research process or its findings.

- **Data Processing and Privacy** – at the same time, under the European General Data Protection Regulation (2016) Informed Consent is the most common (but not only) legal basis for collecting Personal Data (including both Personally Identifiable Information and/or Personally Identifiable Research Data) from "human subjects". Within the context of scientific

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

research specifically it is important that research participants ("human subjects") understand what potential risks they might face as a consequence of the collection of any Personal Data, as well as what steps will be taken to mitigate those risks. The development and execution of a robust **Data Management Plan** constitutes one of those mitigating steps.

Structure and content of your Informed Consent materials

Your Informed Consent materials can be considered as a legal and ethical contract between you and the people who will be providing you with your research data. In most cases this agreement will comprise of Participant Information and Explicit Consent points. The Participant Information is normally a short, clear summary that informs your participant of anything that might affect their willingness to participate in your research. The specific Explicit Consent points list specific points with which your participants can choose to agree or disagree. Bear in mind, when you are giving participants particular choices, that you will need to execute these agreements with precision.

Standard structure of Informed Consent materials

Participant Information	• Your **Participant Information** should clearly summarise what your research aims to do, what participants are asked to do, what risks might arise – including identification – and what steps you will take to mitigate them. Remember to include not just the personally identifiable research data (PIRD) you collect, but also how you will store the Informed Consent forms and any personally identifiable information (PII) therein. • See TEMPLATE 1
Explicit Consent points	• In addition to the Participant Information it is best practice (and sometimes a legal requirement) to include a list of specific **Consent Points** with which your participants can agree or disagree. • Bear in mind that where your participants disagree, you will need to have **practical plans** in place to comply with these specific points. • See TEMPLATE 2

Alternative approaches to Informed Consent

Depending on your research methods and goals, the standard approach outlined above may not appropriate or possible. For example, if you are gathering your research data using an anonymous online survey, the option of removing specific datasets may not be possible – and so this is not something you can offer in your Informed Consent process. In such cases, the Participant Information and Explicit Consent points are replaced by an **Opening Statement** with which participants demonstrate their agreement by clicking the link to the survey (see TEMPLATE 1).

Alternative Informed Consent materials

Opening Statement	• Where your participants are asked to, for example, complete an anonymous online survey, a signed Informed Consent form is not an option. Instead, the Participant Information and Explicit Consent points might be replaced by an **Opening Statement**. In this case a participant's agreement with the terms and conditions of your research can be signified by clicking through to the survey. • Your Opening Statement should ensure that your participants are aware of what your research is about, and what is expected of them before they click through to the survey. • Make sure that your participants can leave the survey or skip questions in line with your Opening Statement – and that your Opening Statement is clear on this. • Make it clear that by clicking through to the survey participants are agreeing to conditions.
Verbal Consent	• In some circumstances it might be necessary to use other Informed Consent approaches – such as verbal consent and/or consent of a Gatekeeper.
Debriefing Information	• Where deception is required for your research, Informed Consent has technically not been given. In such cases you are advised to debrief your participants, explaining why they were deceived and how, and seek Informed Consent again after the debrief.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

Where it is not possible to seek Informed Consent at all – e.g.: because your method involves covert observation, relies on existing datasets, or is collected from the public domain – steps to ensure the safety of your participants are nevertheless required. For example, you can make sure that the party or parties providing your data are permitted to do so, collect information on the original informed consent process, or demonstrate that you understand how combining multiple datasets might lead to unintended consequences and the steps you will take to avoid this.

Please contact your Faculty Data Steward or the TU Delft Privacy Team, or consult our Guidance Notes on completing the HREC checklist for more information.

Executing Informed Consent agreements

Like any contract between parties, your Informed Consent agreement needs to be managed and executed in perpetuity, so make sure that you have plans in place to honour the agreements you have made – including what happens if you or another member of the research team moves elsewhere. Bear in mind also what is and is not executable in practical terms. For example, if you are seeking approval to use personal names with quotes in any publications, then it is unlikely that you can assure anonymity of stored data. Equally, if you agree with participants to use actual names in any kind of publication, it is best practice to obtain additional, specific approval from named participants prior to publication.

It is critical here that the risks and mitigating steps you identify in your HREC checklist and Data Management Plan are consistent with the agreement you make with your participants. It is your job as the (Responsible) Researcher to ensure that your participants are made aware of any potential risks which they may not themselves foresee. In relation to any Personal Data you may be gathering for administrative purposes and/or as research data, it's equally important that this agreement is in line with how you will manage your data in practice.

To this end, you must make sure that the information across your HREC application documents is consistent and aligned.

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

TEMPLATE 1: Participant Information/Opening Statement

Key points to include	Suggested text
1. Level (eg: Masters, PhD, research) purpose, potential outcomes and implications of the study 2. The role of TU Delft and any third parties including funding body 3. Who participants are (eg: children, experts, students in a dependent role to the researcher) 4. What exactly what they are being asked to do 5. What if any Personal Data (Personally Identifiable Information and/or Personally Identifiable Research Data) will be collected, and how it will be used, published and managed. This should include clarity on: o how the data you collect will be used during the research o safeguarding personal information, maintaining confidentiality o de-identifying (pseudo/anonymising) data o controlling access to data, data archiving and reuse o (possible) data publication and dissemination, and o data archiving and the retention period for research data or criteria used to determine that 6. What physical, emotional or reputational risks might arise from participation either during or after the study, and what steps will be used to mitigate these risks 7. Participants' right to refuse to answer/withdraw from the study at any time 8. The right (or otherwise) of participants to request access to and rectify or erase personal data 9. Any remuneration for time/compensation for travel 10. Contact details of the Responsible Researcher and procedure for making complaints. **Note: the TUD Human Research Ethics Committee should not be included as a contact and does not deal with participant complaints.**	You are being invited to participate in a research study titled [*Name of your research*]. This study is being done by [*Name of Researcher(s)*] from the TU Delft [*include also any collaborating partners including internship provider and/or funding body*]. The purpose of this research study is [*provide participants with a short statement about the research*], and will take you approximately [*XX*] minutes to complete. The data will be used for [*provide list of intended uses, including publication, application and teaching*]. We will be asking you to [*provide summary of what kinds of questions or tasks participants will be faced with*]. As with any online activity the risk of a breach is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by [*be clear on whether the survey is completely anonymous, and/or whether IP addresses or other Personal Data will be collected. If so describe how you will safely store data, how confidentiality will be secured and how it will be anonymised*]. [*mention Open data specifically if applicable*] Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions. [*Include also clarification on whether data can be removed within a given timescale. This will not be possible where surveys are completely anonymous*] [*Provide contact details for corresponding and Responsible Researcher*] [*If participants are agreeing to this Opening Statement by clicking through to an (anonymous) online survey, this should also be clear in the Opening Statement.*]

Back to text

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

TEMPLATE 2: Explicit Consent points

Please make sure that you select (and amend as necessary) any Explicit Consent points which are relevant to your study and exclude those which do not apply. You should also add further points and necessary to address your specific research situation.

PLEASE TICK THE APPROPRIATE BOXES	**Yes**	**No**
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION		
1. I have read and understood the study information dated [*DD/MM/YYYY*], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
Separate 'yes/no' tick boxes allow you to make sure that your participant is actively affirming their consent. If the participant wants to tick the no box this allows you to clarify any points the participant is unsure about. ***If this is not applicable for your study, then remove the 'no' box.***		
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	☐	☐
This point should be modified accordingly where a legal guardian will be giving consent, and/or where a participant, outside the context of the research is in a dependent or subordinate position to the researcher.		
3. I understand that taking part in the study involves: [*see points below*]	☐	☐
Provide briefly what is relevant from the following: • *Describe in a few words how information is captured, using the same terms as you used in the Opening Statement, for example: an audio-recorded interview, a video-recorded focus group, a survey questionnaire completed by the enumerator…* • *For interviews, focus groups and observations, specify how the information is recorded (audio, video, written notes)* • *For questionnaires, specify whether participant or enumerator completes the form* • *For audio or video recordings, indicate whether these will be transcribed as text, and whether the recording will be destroyed. NB: Please consider whether audio or video recording is essential to your research.* ***As far as possible you should aim to minimise the Personal Data (PII and/or PIRD) you collect.***		
4. I understand that I will be compensated for my participation by […]	☐	☐
Include reasonable compensation for time or travel (if any) and how this will be disbursed		
5. I understand that the study will end […]		
Please add the anticipated timing or how the date will be determined		
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		
6. I understand that taking part in the study involves the following risks […]. I understand that these will be mitigated by […]	☐	☐
• *Describe in a few words any risks associated with participating in the study,* ***other than those relating to Personal Data and the potential for re-identification****, for example: physical or mental discomfort; risks for participants in a surbordinate position to the researcher* • *Describe also what steps you will take to mitigate these risks – such as device certification, or the ability to ask for the experiment to stop at any point*		
7. I understand that taking part in the study also involves collecting specific personally identifiable information (PII) […] and associated personally identifiable research data (PIRD) […] with the potential risk of my identity being revealed […]	☐	☐

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
• *Please list which PII and/or PIRD will be collected and summarise (if) any potential risks of re-identification (eg: public/professional reputation)*		
8. I understand that some of this PIRD is considered as sensitive data within GDPR legislation, specifically [*see points below*]	☐	☐
List the relevant issues: eg: • *religion, political views* • *Data concerning criminal activities will/may be collected and processed* • *Research has a Data Processing Impact Assessment (DPIA) in place*		
9. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach […]	☐	☐
Provide brief summaries of the mitigating measures to be taken (eg: anonymous data collection, (pseudo-) anonymisation or aggregation, secure data storage/limited access, transcription, blurring, voice modification etc)		
10. I understand that personal information collected about me that can identify me, such as [*e.g. my name or where I live*], will not be shared beyond the study team.	☐	☐
11. I understand that the (identifiable) personal data I provide will be destroyed […]	☐	☐
Please add the anticipated timing or how the date will be determined		
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION		
12. I understand that after the research study the de-identified information I provide will be used for [*see points below*]	☐	☐
• *Please list any planned or possible outputs, e.g. reports, publications, website, video channel. This should also include any planned application (such as decision-making, policy- service- or product development. Consider any secondary use and whether knowledge sharing and benefits sharing needs to be considered, e.g. for indigenous knowledge.* • *Please be explicit if the publication of recognisable images, quotes or other PIRD are anticipated and ensure specific agreement on this*		
13. *If you want to use quotes in research outputs then add extra question:* I agree that my responses, views or other input can be quoted anonymously in research outputs	☐	☐
14. *If you want to use named quotes, then add extra question:* I agree that my real name can be used for quotes in research outputs	☐	☐
15. *If written information or other works are provided by the participants (e.g. in a reflection or other diary, or as images etc.) please check* https://www.tudelft.nl/library/copyright/c/what-is-copyright) *for information on copyright, and/or contact the Copyright Team for further information at* copyright-lib@tudelft.nl *and insert appropriate consent questions accordingly.*	☐	☐
D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE		
16. I give permission for the de-identified [*specify the data*] that I provide to be archived in [*name of data repository/ies*] repository so it can be used for future research and learning.	☐	☐
17. *If relevant please add:* I understand that access to this repository is [*open/ unrestricted/ restricted only to ..... according to the access status to be conferred.*]	☐	☐
If different from Explicit Consent points 8 and 9 above:		

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
• *Specify in which form the data to be stored will be deposited, e.g. anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit.* • *Specify whether deposited data will be anonymised, and how. Make sure to describe this in detail in your Opening Statement* • *Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.* • *Include when the data will be deleted – or provide criteria for when and how that decision will be made*		

Signatures

_____ _____ _____

Name of participant [printed] Signature Date

[Add legal representative, and/or amend text for assent where participants cannot give consent as applicable]

I, as legal representative, have witnessed the accurate reading of the consent form with the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

_____ _____ _____

Name of witness [printed] Signature Date

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____ _____ _____

Researcher name [printed] Signature Date

Study contact details for further information: [*Name, phone number, email address*]

Back to text

Funded by the European Union

This project has received funding from the European Union under the Horizon Europe Research & Innovation Programme (Grant Agreement no. 101123467 MultiCare). Views and opinions expressed are however those of author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them.