MED1stMR
Mixed Reality Training

TRAIN
[SKILLS. RESILIENCE. PERFORMANCE]
SAVE LIVES

D1.2

Ethical Guidelines and Procedures

Version
V1.0

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MED1stMR

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Versions

Version	Date	Author(s)	Description
V0.1	15/08/2021	Marie Ottilie Frenkel (UHEI) Cornelia Wrzus (UHEI) Anke Baetzner (UHEI) Yannick Hill (UHEI)	Concept for necessary information
V0.2	13/09/2021	Marie Ottilie Frenkel (UHEI) Cornelia Wrzus (UHEI) Anke Baetzner (UHEI) Yannick Hill (UHEI)	First Draft (full)
V0.3	27/09/2021	Marie Ottilie Frenkel (UHEI) Cornelia Wrzus (UHEI) Anke Baetzner (UHEI) Yannick Hill (UHEI)	Integration of internal feedback
V1.0	30/09/2021	Vendula Rajdlova (AIT)	Final editing and upload

Report Review

Version	Date	Reviewer(s)	Statement
V0.3	22/09/2021	Thomas Sauter (UBERN)	Request to add the statement that every research institution may also be able to request ethical approval from their local ethics committee.
V0.3	22/09/2021	Consortium and advisory board	Review
V0.3	29/09/2021	Ethic Committee	Review
V1.0	30/09/2021	Helmut Schrom-Feiertag (UHEI)	Final review

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List of Acronyms and Abbreviations

Acronym/ Abbreviation	
GDPR	General Data Protection Regulation
MFR	Medical first responder
MR	Mixed reality
VR	Virtual Reality

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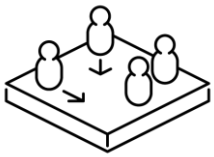
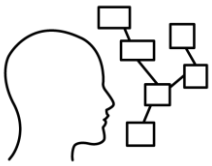
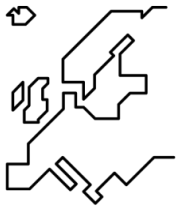
Relation to Objectives

Objective	Description
	**Obj. 1: Pioneering MR training approach for enhanced realism** The aim of this project is to develop an evidence-based training system based on MR. This implies that a strong empirical basis needs to be developed. This basis should include whether the training 1) simulates reality to a sufficient degree and 2) stimulates the development of relevant skills for MFRs. Both of these aspects will be examined with scientific studies. Because all of these studies will involve human participants ethical guidelines need to be adhered to carefully.
	**Obj. 2: Effective training scenarios and a training curriculum** The agile development of the training curriculum entails that MFRs first indicate what specific requirements an MR training needs to fulfil. Then, the MFRs need to test the several iterations of the MR training system in its development in order to provide the necessary feedback to shape the development according to their needs and experiences. Both of these steps (i.e., the initial exploration and the stepwise development) need to take place in structured studies to ensure the validity of the feedback. Thus, empirical studies will be fundamental to this development. As illustrated for Objective 1, such studies will inherently focus on human subjects, deeming proper ethical guidelines necessary for this this objective as well.
	**Obj. 3: Physiological signal and trainee behavior feedback loop and smart scenario control** The aim of this objective is to ensure that the participants of the MR training are exposed to sufficient amounts of psychophysiological stress to simulate their real-world activities, while at the same time being able to protect them from potential negative consequences of too high stress. This will enable trainers to modify the training scenarios to meet the necessary requirements in a safe environment. To reach this aim, we need to establish reliable indicators of experienced stress that can be coupled to the MR training technology. To do so, we need to examine 1) what stimuli trigger stress-responses in MFRs, 2) what parameters reflect reliable real-time indicators of stress, and 3) what sensors/tools validly measure these signals. These steps require the assessment of trainees' psychophysiological responses and behaviors.
	**Obj. 4: Position the pioneering MR training approach across Europe** Given the strong research-focus of this deliverable, there is no direct relation to this objective.

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Executive Summary

The aim of this deliverable is to formulate the ethical guidelines for the scientific studies conducted within this project. Using these guidelines, we submitted a superordinate ethical request for this project specifying the research agenda for first research phase (i.e., identifying end user needs and current training curricula). For this aim, we provide an overview of the necessary information for the ethical request procedure as well as templates for the participant information and informed consent form necessary for each study. Given that these procedures are essential for all research activities, this deliverable provides an important foundation for the project.

Relation to other deliverables and tasks in MED1stMR

Table 1: The work and the document build on results from the following deliverables

No.	Title	Basis for
9.1	H – Requirement No. 1	The ethical guidelines reflect a synergy of the individual ethical requirements. All individual elements are implemented and utilized for the ethical request of the entire project.
9.3	POPD – Requirement No. 3	
9.6	GEN – Requirement No. 6	

Table 2: The results of this work will be incorporated into following work and developments

No.	Title	Basis for
9.2	H – Requirement No. 2	The ethical guidelines for the research agenda of the project will also be reflected in all the ethical deliverables of project. Thereby, congruent guidelines will be established that hold across all elements of the project.
9.4	EPQ – Requirement No. 4	
9.5	M – Requirement No. 5	
9.7	GEN – Requirement No. 7	
9.8	GEN – Requirement No. 8	

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1 Ethical Approval Procedure

1.1 Introduction

In order to conduct empirical studies involving human participants (end user involvement also see D1.4), researchers are required to have their research protocol inspected and approved by an independent ethics committee. This committee will ensure that the participants are protected under the guidelines stated in the Declaration of Helsinki as well as the data is treated according to the GDPR. Only if the ethics committee has provided written statement that all necessary information (see Section 1.2) has been reviewed and that the study protocol does not contain any conflict with the ethical guidelines, the study may be conducted.

1.2 Necessary Information

In this section, we will outline the specific pieces of information that need to be reported to the ethics committee for every study under one central superordinate request for the entire project. Note that these requirements are mandated by the Faculty of Behavioral and Cultural Studies of Heidelberg University, Germany. These guidelines were chosen because this ethics committee is the corresponding board for the team leading the work packages which are heavily focused on research (i.e., WP3 – Development of innovative training programs and WP6 – Field trials). Furthermore, this ethics committee works in accordance with the international guidelines of the Declaration of Helsinki as well as the European GDPR. Therefore, the superordinate request that covers a majority of the studies will be written in accordance to these guidelines. However, each research partner may additionally or solely file an ethical request in agreement with their local ethics committee. Independent of the local criteria, the parties ensure to adhere to the specified ethical guidelines, especially concerning vulnerable participant groups, deception, psychological strain, and physical risks.

1. Researchers Involved **Please list the full affiliation, specific role (e.g., PI or data collection supervisor), and contact information of each researcher involved. Mark if they are belonging to your institute or to another consortium member.** **Answers:**
2. Study Description **Please specify** **a) the specific research question (in light of the theoretical background and previous findings)** **b) the purpose of your study** **c) the design of the study (and if a manipulation is used, explain it)** **d) what exactly are the participants asked to do during the study**

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e) what data is being obtained with specific variables measurement instrument **f) when (e.g., July 2021-December 2021) and where (i.e., online or in a specific place/institution) the data collection will take place** **If possible, attach the full "participant information sheet" and "informed consent form" that participants receive before agreeing to participate in this study.** **Answers:**
3. Intended Sample **Please specify** **a) where the sample is taken from and how large it is** **b) recruitment approach, e.g., newspaper, NGOs** **c) type and amount of compensation** **Answers:**
4. Data Processing **Please specify** **a) how the data is stored and who can access it** **b) whether personally identifiable data is collected (e.g., video/voice recordings, email addresses etc.)** **c) how the data will be analyzed** **d) how the results of the study will be published (if possible, please specify the intended journal's name)** **Answers:**

1.2.1 Researchers Involved

For each ethical request, all researchers who are involved in the study need to be listed. This includes the researchers' names, their roles in the study or project, affiliation, and contact info (e.g., email address and phone number). This step is necessary for the transparency of the research process as well as reflecting who will have access to the generated data. This information will also be provided to the participants so that they can make a fully informed decision on whether they are willing to share their data with the parties involved. For MED1stMR, only partners from the consortium will be involved

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in the studies and have access to the data. In exceptional cases, external parties may be requested to support the data analysis (e.g., a laboratory specifically focused on extracting stress hormone levels from saliva samples). However, these parties are also obliged to follow the same ethical standards as the partners from the consortium.

1.2.2 Study Description

The ethical board will also review the rationale and planned procedure for the planned studies. This means that all partners need to provide detailed descriptions of their study before it can be voted on regarding potential ethical concerns. This includes all of the pieces of information described below.

First, the specific research question needs to be defined. This research question needs to be explained as a logical consequence of the existing empirical and/or theoretical insights from the relevant scientific literature. The specified purpose of the study should therefore add on the existing literature and move the field forward either theoretically or new practically.

Second, the research design needs to be explained. The design should be specified regarding whether the study consists of a survey or an experimental design. If an experimental design is implemented, a precise description of the experimental manipulation has to be provided. The description of the study design should also list *all* variables that will be assessed during the study alongside the scale or instrument that is used for the assessment. This includes (among others) demographic variables, psychological characteristics indicated on a questionnaire, physiological factors like heart rate, and behavioral data during MR training. A full list of the collected variables information will also be provided to the participants for a full informed consent. Furthermore, an explanation of what the participant will be required to do is mandated. This should include everything that the study asks the participants to do in preparation for the study, during the actual data collection, and following the data collection. Finally, information on the exact location (e.g., in a laboratory of a university, training facility of an end-user partner, or online) and the timeframe of the data collection have to be provided.

1.2.3 Sample & Recruitment

A central topic for the ethical guidelines focuses on the individuals who are supposed to participate in the studies. Given our responsibility to take particular care of vulnerable groups (e.g., minors or clinical groups), exactly who the intended sample consists of and how these individuals are recruited will be examined. Therefore, the sample description for the ethical approval needs to include information on where the sample is taken from and how many individuals are supposed to be recruited. This involves specification of potentially vulnerable groups. Given that this project aims to develop MR training for MFRs, the recruitment strategy will likely never target such groups explicitly. Only in exceptional cases, such groups may be recruited (e.g., young teenagers who are highly experienced with performing in MR and/or VR environments). These groups will be treated with extra care including the active involvement of their caretakers for the informed consent and conducting the study. Such procedure will have to be described explicitly if such a group is involved in the study. Given that important parameters, such as different ages of consent, may differ across different study locations, the specification of the sample will always have to be provided. Furthermore, the recruitment strategy will also be evaluated. This entails any means by *how* the participants are informed about and invited to

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the study. To ensure voluntary participation, the invitation that will be sent out to the recruits will have to be submitted for the ethical request. If participants are compensated for their participation, the type (and if financial in nature, the amount) will have to be provided.

1.2.4 Data Processing

The ethical approval procedure also focuses on how the generated data will be processed. This includes an explanation on how the data will be stored (e.g., on a hard drive or secured server) and who will be able to access the data (and how). Additionally, the collection of potentially identifiable information (e.g., video recordings or email addresses) will have to be justified. Only if such data is absolutely necessary for the study, such data will be collected. If such data is collected, it always needs to be stored separately from other data that is collected in the context of the same study. Moreover, video and audio recordings should be deleted once they have been analyzed or transcribed (no later than 90 days after being collected). Email addresses to contact participants for repeated assessments over a longer period will be deleted (and physical copies destroyed) once the data collection has been completed. In case that identifiable information is collected, the participants will be asked to sign an additional consent form specifying how the data will be handled. This means that the participants may decline the collection of their personal data. Only if the permission of the participants has been provided, such data will be collected. Note that each study will make use of pseudonymization of the data. This means each participant will generate their own code (e.g., consisting of 2 digits and 2 letters). This code ensures that different types of data can be matched to a specific individual without being able to identify who that individual is. That is, the specific person can never be associated with a specific set of data. Participants will also be notified that this code should not be guessable easily by others. Furthermore, this code enables participants to exercise their right to have their data removed even after the data has been collected because they will be able to identify what data belongs to them.

The data processing information will also include how the data will be analyzed. Although precise statistical methods may not be possible to address before the actual data has been generated, the specifications should include what groups are compared to each other or whether the analysis of the data occurs on an individual-level or group aggregate. This step also includes the potential dissemination of the results. This means that it should be mentioned whether the data will be used for a potential publication in a scientific journal or a similar type of public dissemination (e.g., conference contributions). The dissemination information will also be passed on to the participants before they agree to take part in the study.

1.2.5 Checklist

The final element of the ethical approval is a checklist (see below) with the most crucial elements for ethical considerations. This includes (among others) the risk assessment of the study, data protection, and insurance claims. If the answer to any of the questions corresponds to a field marked in red, a detailed explanation as to why this decision is absolutely necessary will have to be provided.

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I. Checklist		
	Yes	No
1. Voluntary participation: Do the participants take part in the study voluntarily?	☐	☐
2. Consent: Are you intending to sample any individuals who cannot actively provide informed consent? This may include individuals who are under the age of 18, not eligible to provide informed consent by law or due to medical or psychological reasons.	☐	☐
3. Vulnerable participants: Do you intend to specifically recruit individuals who may be particularly vulnerable (e.g., clinical samples, people with learning disabilities, individuals from forensic settings, individuals suffering from dementia, individuals living in a care institution, or individuals with physical handicaps)?	☐	☐
4. Discontinuing participation: Will the participants be informed, prior to starting the study, that they have the right to discontinue their participation at any point without having to state any reason and without any negative consequences?	☐	☐
5. Inclusion and exclusion criteria: Are there any specific reasons for including or excluding participants?	☐	☐
6. Informed consent: Will the participants provide active informed consent in written form?	☐	☐
7. Debriefing: Will the participants be fully informed about the content and the aim of the study before they agree to participate?	☐	☐
8. Deception for participation: Is it necessary that the participants take part in the study without being fully informed in advance? For example, no informed consent will be used due to an observational study in a natural setting.	☐	☐
9. Active Deception regarding content, purpose, method, and/or setting of the study: Will the researchers have to actively deceive the participants regarding the content, purpose, method, and/or setting of the study? For example, a cover story will be used in order not to give away vital information that can change the outcome of the study?	☐	☐
10. Intimate or stigmatizing information: Will the study contain questions regarding intimate and sensitive topics (e.g., traumatic experiences, sexuality etc.) or topics that can be perceived as stigmatizing by others (e.g., illegal behaviors like drug consumption, addictive behaviors, or political standpoints)?	☐	☐
11. Psychological strain: Is it probable to assume that the participants may experience psychological strain, anxiety, exhaustion, or other negative effects due to this study?	☐	☐
12. Physical risks: Does this study involve any invasive measurements? Will the participants be exposed to potentially straining (e.g., blood or saliva measures) or potentially damaging procedures? Will physical pain be induced? Do you expect any undesired side effects?	☐	☐
13. Substance administration: Will the participants be administered any medicine, placebos, or other substances?	☐	☐
14. Confidentiality: Will the data of the participants be treated confidentially and saved either anonymously or under a pseudonym?	☐	☐
15. Data protection: Is the data protection for all data generated in this study guaranteed?	☐	☐
16. Data protection information: Will the participants be informed about the steps that are implemented to guarantee the protection of their data?	☐	☐
17. Right to remove data: Can the participants request the deletion of their specific data within a specific timeframe following the data collection?	☐	☐
18. Insurance coverage: Will there be insurance coverage for the participants travel to the study location or will they be informed that there is no insurance coverage beforehand?	☐	☐

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2 Participant Information & Informed Consent

2.1 Participant Information

In order to ensure that the participants can provide informed consent for the study, they need to receive exhaustive information on the contents of the study, who is involved in the research project, what exactly will be asked of them, and how their data will be treated. Therefore, every study needs to provide the participants with this information in written form. Because the specific information may vary substantially between studies, we developed a template that covers all the necessary information:

Add a header containing the name, affiliation, and contact of the study lead as well as the Grant Agreement ID

Study Information for Participants

[INSERT NAME OF THE STUDY]

Introduction

The current study is part of a series of studies conducted within the EU Horizon project MED1stMR (Grant Agreement ID: 101021775). This study is led by [INSERT INSTITUTIONS RESPONSIBLE FOR THIS STUDY AND CONTACT INFORMATION]. You have been invited to participate in this study. Before you agree to participate, please read carefully through the information provided below. Do not hesitate to ask the researchers about anything concerning your participation and the provided information. You may approach the researchers at any time throughout the entire data collection process and after the study has been completed.

Why do I receive this information?

- **Explain that the reader is being invited to participate in the research and why they in particular are being invited (e.g., they work in a particular company) and receive this information.**
- **Explain who is involved in the research. Name all internal researchers and their affiliations. Clarify their responsibilities.**
- **Specify the start and end dates of the research.**

Do I have to participate in this research?

Participation in the research is voluntary. However, your consent is needed. Therefore, please read this information carefully. The research team is available to offer additional explanations and clarifications. Only after you decide if you want to participate. If you decide not to participate,

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you do not need to explain why, and there will be no negative consequences for you. You have this right at all times, including after you have consented to participate in the research. Your withdrawal from the study means that your data will be deleted and not used for further analyses.

Why this research?

- **What is the purpose of this research? Use accessible language and neutral terms.**

What do I have to do during the research?

- **Indicate that the reader will first be asked for consent to participate.**
- **Describe step by step what the research will involve for participants. The level of detail depends on the nature of the research.**
- **Clarify the global nature of the research (content of questionnaires, tasks, observation, etc.) such that the reader can make a deliberate, informed choice concerning their participation.**
- **If applicable, explain why audio or video recordings will be made.**
- **If applicable, explain that an experimental procedure will be used and what it entails. If it is necessary, you may choose not to disclose this information before the start of the study. However, in this case, you are obligated to fully inform the participant immediately after the study.**
- **Provide the expected duration of participation (i.e., the amount of time taken up by the research). If the research consists of multiple parts, indicate how long each part takes. If there are multiple contact times, indicate how often (e.g., monthly for 1 year).**
- **Indicate what compensation is provided and why. If no compensation is provided, mention this explicitly.**

What are the consequences of my participation?

- **Briefly describe any direct benefits of the research to the participant (besides compensation). If there are indirect benefits, concerning the expected knowledge gained, you may mention this as well, but it should be clear that research outcomes cannot (usually) be guaranteed.**
- **If applicable, describe the disadvantages of participation, particularly any negative effects and other forms of mental or physical discomfort that the research may entail. Also indicate how high the chance is that these effects will occur. Explain how you will deal with negative effects and with potentially unpleasant research outcomes.**

How will we treat your data?

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- **State the purpose of the data processing.**
- **Explain the (type of) data that will be processed (e.g., collected, prepared, analyzed). How will it be processed? By whom? Where? Which sensitive (personal) data will be processed? Indicate all data processing risks.**
- **Explain the pseudonymization procedure (i.e., how will the code be generated). Describe how the research data will be secured and protected. Which measures have been taken to preserve the confidentiality of the participants (or others potentially affected by the research)?**
- **After which date is the link between participants' identity and their data removed? This includes all identifiable information, including video or audio recordings and email addresses. Also, state explicitly that the personal data is stored on a safe server at the AIT, which can only be accessed by the research organizations (AIT, UHEI, UBERN, UMU, and MUL) of the consortium.**
- **Participants have the right to access, rectification, and erasure of their personal data. Explain until when, and how, participants can ask for a copy of their personal data, have erroneous personal data corrected, and have their personal data withdrawn.**
- **If you intend to make data public, specify which data and how they will be treated.**
- **If you intend to make data available for reuse by people or institutions outside of the research team, indicate how this will be done and who is responsible for what.**
- **State that the participants have the right to be informed about the general outcomes of the study. This information can be obtained from the principal investigator.**

Add:

Do you have questions or concerns regarding the handling of your personal data? You may also contact the Data Protection Officer of MED1stMR: Michael Löffler dpo@ait.ac.at

As a research participant, you have the right to a copy of this research information.

2.2 Informed Consent

After the participants have read through the study information and been given the chance to ask any question for clarification, they will be asked to sign the informed consent form:

Add a header containing the name, affiliation, and contact of the study lead as well as the Grant Agreement ID

Informed Consent

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[INSERT NAME OF THE STUDY]

- **I have read the information about the research. I have had enough opportunity to ask questions about it and time to make an informed decision regarding my participation.**
- **I understand what the research is about, what is being asked of me, which consequences participation can have, how my data will be handled, and what my rights as a participant are.**
- **I understand that participation in the research is voluntary. I myself choose to participate. I can stop participating at any moment. If I stop, I do not need to explain why. Stopping will have no negative consequences for me.**
- **Below I indicate what I am consenting to.**

Consent to participate in the research:

☐ **Yes, I consent to participate**

☐ **No, I do not consent to participate**

Consent to make audio / video recordings during the research:

☐ **Yes, I consent to make audio / video recordings of me as a participant in the research.**

☐ **No, I do not consent to make audio / video recordings of me.**

Consent to processing my personal data:

☐ **Yes, I consent to the processing of my personal data as mentioned in the research information. I know that until dd-mm-yyyy I can ask to have my data withdrawn and erased.**

☐ **No, I do not consent to the processing of my personal data.**

Participant's full name:	Participant's signature:	Date:

Full name of researcher present:	Researcher's signature:	Date:

The researcher declares that the participant has received extensive information about the research.

You have the right to a copy of this consent form.

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3 Implementation

Using the ethical procedures outlined in this deliverable, we have drafted a superordinate ethical request for the first wave of studies within this project. This request is currently under review by the ethics committee of the Faculty of Behavioral and Cultural Studies of Heidelberg University, Germany. The aim of this superordinate request is to combine as much overlapping information as possible for studies with a similar aim. Specifically, the first wave of studies within this project will examine the end-users' needs for MR training, their current training curricula (and their evaluation thereof) and include surveys on MFRs' experience of the current training programs. Once the superordinate request has been approved, each specific study that will be launched only needs to submit an amendment specifying whether any additional variables will be assessed or procedures will be implemented that deviate from the already approved ones. Additionally, the specific participation information and informed consent forms will have to be adjusted. This procedure will enable us to efficiently launch several studies using similar designs and contribute to similar aims.

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