Title

H - Requirements No. 1

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Deliverable 9.1 H – Requirements No. 1

WP9 - Ethics requirements

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Executive Summary

This deliverable aims to detail the informed consent procedures foreseen for RITHMS Project's activities. This document is connected to previous D9.2-POPD.Requirement N.2 and to the Ethics Protocol (D7.2), which provides the Consortium with ethical guidelines throughout the Project's lifespan.

RITHMS Consortium will comply with all European and international legislation irrespective of the country in which the activities are carried out.





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1. Introduction

Deliverable 9.1 aims to explain and make publicly available the informed consent procedures that will be implemented for the research participants during RITHMS Project.

2. Informed consent

Informed consent is a key principle of ethical research; therefore, RITHMS Consortium has carefully considered how consent could be gained, including the extent to which it is possible to get in contact with data subjects.

The obligation to provide information to data subjects is independent of the legal basis for processing personal data. Without information, data subjects would likely not be in a position to exercise their rights, as described in Articles 15–22 GDPR. Information plays an important ethical and legal role in research involving personal data, as the lack of information increases the potential harm for data subjects.

In particular, informed consent is the legal basis for the collection and processing of personal data related to the interviews, surveys, questionnaires, focus groups, and workshops foreseen in different Work Packages, as detailed in D9.2.

They will be mainly used for qualitative research. Qualitative research tends to involve sensitive areas and processes of society that often necessitate more direct access to and intensive interaction with respondents, benefiting from an established relationship of trust between the researcher and the respondent, such that the data produced tend to be more context sensitive. Full anonymisation, so as to exclude the risk of disclosure completely, is an ideal that rarely matches the reality of qualitative data collection, far less than is the case with quantitative data. Not only is the risk of violation of privacy more probable with, for example, in-depth interviews, the collected data usually contain a density of information on the participants (most notably with video, audio, or image data) and, therefore, carry considerable disclosure risk. Furthermore, de-identifying of qualitative data may be complex and costly and might result in reduced usability of the data (e.g., an interview with a high-rank police officer with a privileged access to the required information should be recorded as that, because the rank is important, but it may be easy to relate the rank in a concrete police force with the real identity). In sum, it is often the case that qualitative data cannot be fully anonymised or sufficiently pseudonymised without compromising their analytical potential.

Quantitative data, on the other hand, are easier to anonymise and the process is less costly and time-consuming. Further, the disclosure risk and the risk of compromising analytical potential and data usability by de-contextualisation is considered lower. Mainly with respect to qualitative data, best practice in de-identifying has not yet been firmly established in the social science research community. Thus, to make up for these current inadequacies and to protect participants, as well as to comply with





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data protection legislation and assure long-term preservation of the data, it is recommended to seek a more formalised informed consent from participants in qualitative research.

The only personal data that might be collected are: name, age, sex, nationality, contact information (email), profession, responsibility, and employer. Neither the participants nor their employers will be identified in any publication. Occupation and name of the employer might only be identified in non-publicly available reports. In case a more general reference to the profession (such as high-rank police officer) and name of the employer are needed in publications, consent will be specifically asked for.

The protection of personal data is considered a fundamental right already in the European Convention on Human Rights of 1950. The Charter of Fundamental Rights of the European Union of 2000 regulates the processing of these data on the basis of the consent of the person concerned (Art. 8). The GDPR prohibits, with various exemptions (for example, scientific research and archiving in the public interest), all processing of not anonymised personal data without the consent of the data subject (Article 6(1)(a)) and thereby increases the accountability of the researcher. It defines the concept of 'informed consent' as follows: 'Consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her (Article 4(11)). Legal requirements related to consent will be further addressed in D1.1 – Report on the initial legal requirements (UDC, M6) and D9.3 – AI – Requirement No.3 (IIT, M6).

'Informed consent' is not only a legal requirement, but also one of the founding principles of research Ethics. Its intent is that human participants can enter research freely (voluntarily) with full information about what it means for them to take part, and that they give consent before they enter the research.

Consent should be obtained before the participant enters the research (prospectively), and there must be no undue influence on participants to consent.

The minimum requirements for 'consent' to be informed are that the participant understands what the research is and what they are consenting to. There are two distinct stages to a standard consent process for competent adults:

- Stage 1 (giving information): The person reflects on the information given; they are under no pressure to respond to the researcher immediately.
- Stage 2 (obtaining consent): The researcher reiterates the terms of the research; the person agrees to each term (giving explicit consent) before agreeing to take part in the project as a whole. Consent has been obtained.

For consent to be valid, the data controller must be able to demonstrate that informed consent has been gained from users whose data will be processed (Article 7 of the GDPR). The following documents, developed in accordance with models of other European projects, adapted to the specific





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tasks of RITHMS, can be found below as annexes (the provisional versions were also included in D9.2). They aim at providing each participant with a comprehensive explanation of the purpose of the research, together with all the details one would expect to find in a consent information sheet.

ANNEX 1. Interviews and Focus-Group Workshops: Template Participant Information Sheet. ANNEX 2. Online Surveys, Questionnaires or Tasks: Template Participant Information Sheet.

These documents will ensure that procedures for recruitment are carefully and consistently implemented. Potential participants will be fully informed of the details for the research and their part in it. Interviewers will be fully briefed and prepared in terms of how to approach, recruit and deal with participants, how to answer any questions relating to the information sheet. A schedule of questions is provided to ensure scientific and ethical rigour through both consistency and appropriate flexibility.

Since no sensitive personal data will be collected or processed, approvals or opinions of the relevant data protection officers are not necessary in relation to the data that will be collected in either WP1, WP2 or WP6.





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Annex 1. Interviews and Focus-Group Workshops: Template Participant Information Sheet

The template below contains examples of the main points an information sheet will include. Example wording is italicised, instructions are not. The advisory text will be deleted.

[Study title]

PARTICIPANT INFORMATION SHEET

1. Introductory paragraph

Explain that the prospective participant is being asked to consider taking part in a research project. For example, you could say:

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please, take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why is this research being conducted?

State the background, purpose and aims of the research. Remember to be brief and do not use overly complicated language that a lay person would not understand. Consider what a potential participant would want to know. In case only consortium members participate, this information should be very short.

3. Why have I been invited to take part?

Explain how they have been identified as a potential participant and mention any inclusion or exclusion criteria. You should explain how the participant was chosen and say how many other participants will be recruited. In case of Consortium members, it is enough a reference to this condition.

4. Do I have to take part?

It is important that participants understand that they have a choice about whether they take part. For example, you could say:

No. It is up to you to decide whether or not to take part. You can withdraw yourself from the study, without giving a reason, [and without negative consequences – include if appropriate], by advising me/ us of this decision. [If applicable – The deadline by which you can withdraw any information you have contributed to the research is [insert deadline before publication/ submission of deliverable]. [Please explain what will happen to any data that has already been collected if they decide to withdraw.]





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5. What will happen to me if I take part in the research?

This section should explain what will be involved in your research from a participant's point of view, and in the order they will experience it. This should include:

- how consent will be taken;
- how long the participant will be involved in the research;
- what the activity/ activities will involve e.g., interviewees should normally be told what topics will be covered. It might be helpful to explain the questioning style.
- If applicable: With your consent, I/ we would like to audio record you/ video record you/ take photographs of you [delete as appropriate] because... [give reasons why this is necessary here, e.g., for audio recording: so I/ we can have an accurate record of our conversation].
- how long the research will last (if this is different);
- how often they will need to participate and for how long each time;
- that participants can ask to pause or stop the research activities at any time;
- if any follow-up sessions will be necessary, stating duration and frequencies if it is complicated, it may be easier to include a timeline or a diagram to explain;
 - 6. What are the possible disadvantages and risks in taking part?

Any reasonably foreseeable discomforts, disadvantages and risks need to be stated. Explain how these risks will be addressed. It is important that participants understand how identifiable they will be from the data and from the research outputs.

7. Are there any benefits in taking part?

Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be explained.

For example, you could say: While there are no immediate benefits for those people participating in the project, it is hoped that this research will lead to...

Or There will be no direct or personal benefit to you from taking part in this research.

8. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

Clearly list all types of data that will be collected from participants, where they will be stored, and how long for. Specify any special category data that is to be collected. Identifiable data (including consent forms) will be stored [insert location, security measures and explain how long the data





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collected will be stored]. Other research data will be stored for [x] years after publication or public release of the work of the research.

The researcher [and/ or research team, supervisor, collaborator/ translator/ transcriber/ other authorised personnel...] will have access to the research data.

If applicable: I/ We would like your permission to use this data in future studies, and to share this with other researchers (e.g., in online databases). Explain how identifiable participants will be from this data. It is important that you use language that participants understand when explaining how identifiable they will be from the data. It can be difficult/ impossible to fully anonymise data, particularly qualitative data, and participants may not understand terms like pseudonymisation.

9. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will/may be written up [please describe – academic publications, conference presentations, a report, websites, videos etc.] Explain whether it will be possible for participants to be identifiable from the outputs and clarify whether they have a choice about this.

If applicable: I/ We would like your permission to use direct quotations [and for your name to be attributed to these/ but without identifying you] in any research outputs.

10. Data Protection

The [University/institution/company] is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. It will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available at [include appropriate website].

11. Who is funding the research?

Give details of the organisation funding the research.

12. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this study, please contact [insert primary researcher name and University/institution/company tel. no./ email address] and we will do our best to answer your query. I/we will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Ethics Manager Patricia Faraldo Cabana, University of A Coruna, email patricia.faraldo@udc.es. Further Information and Contact Details





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You should give the participant a contact point for further information. This can be your name, address and telephone number or that of another researcher in the project. The use of personal phone numbers and email addresses should be avoided.

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

[Insert the name of the primary researcher] [Insert the name of the Department] [Insert the postal address], University/institution/company tel: [insert number] University/institution/company email: [insert address]





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Annex 2. Online Surveys, Questionnaires or Tasks: Template Participant Information Sheet (provisional form)

For online research with relatively straightforward ethical issues, such as online surveys or questionnaires, participants' informed consent may be implied by their completion of the survey instead of having a separate consent form. It is still important to provide participants with the information they need to make an informed decision about whether to complete the questionnaire. The following template shall be used as the basis for the information provided to respondents in all online research surveys or tasks. The advisory text will be deleted.

[Study Title]

GENERAL INFORMATION

The aim of this study is to [give details as to the purpose].

We appreciate your interest in participating in this [questionnaire/ online survey]. You have been invited to participate as you are [insert age range and inclusion/ exclusion criteria]. Please read through this information before agreeing to participate (if you wish to) by ticking the 'yes' box below.

You may ask any questions before deciding to take part by contacting the entity who is responsible of the research task (details below).

The University/institution/company is [name]. The person in charge is [name of the researcher], and in collaboration with [other university/institution/company if applicable].

[Please explain what participants will be asked to do in this project]. This should take about xx minutes. No background knowledge is required. [Explain why the data is needed, how it will be used, and by whom, including any third parties who may be given access to that data.]

Do I have to take part?

No. Please note that participation is voluntary. If you do decide to take part, you may withdraw at any point for any reason before submitting your answers by pressing the 'Exit' button/ closing the browser. [If applicable.]

[All questions are optional.] OR [We have included a 'Prefer not to say' option for each set of questions should you prefer not to answer a particular question.]

How will my data be used?

Use one of the following two statements:

We will not collect any data that could directly identify you. OR The data we will collect that could identify you will be [list all data types here – e.g., contact details, age, gender, audio/ video recording, IP address].





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Your IP address [will/ will not] be stored. We will take all reasonable measures to ensure that data remain confidential.

The responses you provide will be stored in a password-protected electronic file on secure servers and may be used in [please describe - e.g., academic publications, conference presentations, reports]. [If applicable - Identifiable information will be deleted as soon as it is no longer required for the research (or explain how long identifiable data will be kept]. Research data will be stored for [x] years after publication or public release of the work of the research.

Who will have access to my data?

[If collecting personal data] The [University/institution/company] is the data controller with respect to your personal data and, as such, will determine how your personal data is used in the study. The [University/institution/company] will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest.

The data you provide may be shared with [add names or general description of entities who may have access to the data and for what purpose, such as collaborators and sub-contractors for the project, including suppliers of tools and services for the project].

[If applicable] We would also like your permission to use the data in future studies, and to share data with other researchers (e.g., in online databases). Data will be de-identified before it is shared with other researchers or results are made public.

The results will be written up for a [scientific article/project report].

Who do I contact if I have a concern or I wish to complain?

If you have a concern about any aspect of this study, please contact [insert primary researcher name and University/institution/company tel. no./ email address] and we will do our best to answer your query. I/we will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Ethics Manager Patricia Faraldo Cabana, University of A Coruna, email patricia.faraldo@udc.es.

Please note that you may only participate in this survey if you are 18 years of age or o
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☐ I certify that I am 18	years of age or	over
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If you have read the information above and agree to participate with the understanding that the data (including any personal data) you submit will be processed accordingly, please tick the box below to start.

☐ Yes, I agree to take part



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