



OneAquaHealth

PROTECTING URBAN AQUATIC ECOSYSTEMS TO PROMOTE ONE HEALTH

Ethics Guidance

A SUMMARY OF ETHICS GUIDELINES FOR QUICK AND EASY REFERENCE
BY THE ONEAQUAHEALTH CONSORTIUM MEMBERS



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Ethics in OneAquaHealth | Generic Guidelines

The researcher must respect the right of each individual to safeguard their own personal integrity, especially if the subject is in a dependent relationship to the researcher.

Protection of participant privacy and confidentiality. This may include using pseudonyms or codes to identify participants, storing data securely, and limiting access to data to only those who need it.

Ensure that participants provide informed consent before initiating any research activities. Participants should be given the opportunity to ask questions and withdraw if they wish to do so.

The recognition of the increased vulnerability of individuals and groups calls for special vigilance and protection is also foreseen.

In case of pilots involving **children and youngsters**, the informed consent will also be explained to their parents or legal guardians, who will consent to their participation. Clarify research confidentiality and obtain consent: as mentioned, children should receive a clear explanation of the research's purpose and what will be expected of them.

Adapt the data collection methodology. The way information is collected should be modified to minimize any distress it may cause to children. Sensitivity and age-appropriate approaches should be employed.

Establish a plan for distress and disclosure response. It is essential to have a well-defined plan in place for addressing any distress experienced by children or if they disclose harm either to themselves or others. Prompt and appropriate action should be taken.

Address barriers to participation. Children may face various forms of discrimination that could act as a barrier in their involvement in research. By actively addressing these difficulties, research opportunities can be extended, enhancing the study's quality.

Minimize harm. Minimize potential harm to participants, animals, plants and ecosystems. Whether physical or psychological, minimizing harm to participants can be achieved through measures such as screening participants for risk factors, offering support resources, and monitoring them for signs of distress.

Ethics Committees. Ensure that such research is reviewed ethically and scientifically by competent and independent research ethics committees and is conducted by competent research teams.

Ensure diversity and inclusivity with a sample population that is diverse and inclusive, and where participants are recruited in a fair and unbiased manner. OAH acknowledges relevant legislation and guidelines pertaining to accessibility to ensure the proper integration and inclusion of all participants and potential users in the project outcomes.

Analyse and report data ethically. The researchers will obtain permission from participants before publishing or sharing any identifiable information, to ensure data accuracy, proper interpretation, and respectful handling of privacy and confidentiality.

Use privacy-protective measures. To protect individuals from the possibility that their personal information is directly revealed or otherwise inferred when datasets are published, shared, combined, or linked (when using online environment and digital tools to obtain data for health-related research)

Develop and implement policies and procedures **to mitigate conflicts of interest** and educate staff about such conflicts.

Compliance with GDP Regulation

Detailed information is provided in D1.4: Ethics guidelines and materials vs1 - Section 5.6. But a good checklist is available in: <https://gdpr.eu/checklist>

Observation of international guidelines for safeguarding the environment, ecosystems, and the biological organisms:

- Using NON-INVASIVE techniques to ensure animal and plant wellbeing, whenever possible and always in the case of vertebrates.
- Ensuring vertebrates will be IMMEDIATELY RETURNED to their environment, as the exercises require mostly observation and identification or collection of blood and faeces samples, avoiding any harm inflicted.
- LIMITING the number of animals involved to a minimum, while maximizing the information obtained from each animal.
- Ensuring that vertebrates WILL NOT BE TRANSPORTED.
- Cleaning the sampling devices between sites to prevent the spread of non-native species or diseases.

How to obtain Informed Consent

Clear affirmative action must be demonstrated through an unambiguous indication, regardless of the method employed to gather consent.

“Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject’s agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject’s acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them. If the data subject’s consent is to be given following a request by electronic means, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.” (Recital 32 of the General Data Protection Regulation (GDPR), that clarifies article 4 GDPR (Definitions) and article 7 GDPR (Conditions for consent))

This means that there is a need to ask participants to actively opt in.

An active opt-in mechanism may include:

- **answering yes to a clear oral consent request;**

Silence, inactivity, pre-ticked boxes, opt-out boxes, default settings or a blank acceptance of terms and conditions are not acceptable.

If there are various purposes or types of processing, consent is needed for each separately with a clear yes for each. Participants should not be forced to agree to all or none.

In the case of children's participation, their parents or legal guardians should receive a tailored informed consent form.

Checklist for gender analysis

Project Stage	Gender analysis
Identification	<p>() Can a gender-inclusive design be drawn up for the co-creation activities?</p> <p>() What is the gender balance in the target public?</p> <p>() Is the project likely to have the same positive and negative effects on different genders?</p> <p>() Are there any social, economic, or political effects that the project will have on different genders in the short term? In the longer term?</p>
Design and planning	<p>() Are project objectives clearly related to practical and strategic gender needs? Have different genders participated in setting those objectives?</p> <p>() Do different genders view the planned activity in the same way?</p> <p>() Are the regulatory policies that will affect what can or cannot be done in the project and/or how it must do?</p>
Implementation	<p>() Are there appropriate opportunities for different genders to participate in project activities?</p> <p>() Are there mechanisms to ensure that the project resources or benefits are not controlled or taken over by one gender? Or by sub-groups, factions, or individuals within/outside the community?</p> <p>() Are project team members trained in gender-mainstreaming? If not, will this happen before activities begin?</p>
Evaluation and monitoring	<p>() Are there separate indicators to measure progress in achieving benefits for different genders?</p>

Gender equality is based on equal treatment and opportunities as defined by the European and UN Policies (e.g., Council Directive 75/117/EEC) and is adapted by the members of this consortium. To comply with these guidelines, the consortium partners will:

- Keep gender balance when selecting participants for co-creation activities and validation.
- Focus on occurring gender issues when preparing the evaluation of all the tools.
- Ensure data collection that is sex/gender specific when appropriate.
- Promote non-sexist language in the documentation generated during the project, especially within the interventions' documents and in the dissemination materials.
- Predict a gender distribution and participation according to the normal distribution of genders at the trial sites.

General Checklist by domain

Research	<input type="checkbox"/> Yes	Do you limit the collection of personal data to only those items that are adequate, relevant, and necessary in relation to the purpose for which they are processed, and do you ensure that they are not used in any manner that is incompatible with such purpose?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Is Informed Consent readily available and in a form that is easily understood by participants?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Do you ensure that you obtain consent from the parent or legal guardian before collecting data from children, young people, or other vulnerable individuals?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	...
	<input type="checkbox"/> No	
Implementation	<input type="checkbox"/> Yes	Do you ensure that participants provided explicit and informed consent before collecting any personal data for research purposes. Do you clearly explained the purpose of data collection, how it will be used, and any potential risks involved?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Do you ensure the personal data are preserved for no longer than is required for the purpose for which the information was collected, acquired, or further processed? Do you have procedures to store the data separately or remove identifiers from data records once they are no longer needed?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Are there security protocols in place for each data set that protect against risks such as loss, unauthorised access, destruction, use, modification, or disclosure?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Regarding research with vertebrates, including fish, birds, and amphibians are you guaranteeing: <ul style="list-style-type: none"> the use of non-invasive techniques to ensure animal wellbeing? the return of the vertebrates immediately to the environment? the use of a minimum number of animals to obtain the necessary information? the non-transportation of animals?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Do you safeguard the identity of the participants before storing or sharing the data related to the project?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	...
	<input type="checkbox"/> No	

A.I model development	<input type="checkbox"/> Yes	Have you prepared a clear documentation containing the AI system's goals, data sources, algorithms, and limitations?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Have you taken into consideration data quality and measures to mitigate bias?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Does the AI model provide clear explanations for its decisions and the underlying reasoning behind them?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Did you include experts from multiple domains (health, environment, social sciences) as well as the potential end users, when developing the AI system and consider their feedback?
	<input type="checkbox"/> No	
<input type="checkbox"/> Yes	Have you ensured the regular monitoring and evaluation of the AI system's performance?	
<input type="checkbox"/> No		
Use of secondary data	<input type="checkbox"/> Yes	Have you clearly defined the research objectives and questions that you want to address using secondary data?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Have you determined the specific types of secondary data you need to answer in your research questions?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Have you identified reputable sources of secondary data that are relevant to your research topic?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Have you evaluated the reliability, validity, and relevance of the secondary data you plan to use?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Have you recognized and documented any limitations or biases in the secondary data you will be using?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Have you provided proper citations and references to acknowledge the original sources of the secondary data?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	Have you applied appropriate analytical techniques to analyse and interpret the secondary data effectively?
	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes	If needed, have you considered collecting primary data to complement the secondary data for a more comprehensive analysis?
	<input type="checkbox"/> No	
<input type="checkbox"/> Yes	Have you compared your findings with other sources of secondary data or primary research to validate the consistency and robustness of your results?	
<input type="checkbox"/> No		

Annex II – Informed Consent Package

The next eleven pages (pp. 55 – 65) make up the “Informed Consent Package” that has been prepared to assist consortium members who wish to conduct research involving human participants.



OneAquaHealth 

PROTECTING URBAN AQUATIC ECOSYSTEMS TO PROMOTE ONE HEALTH

Grant Agreement: 101086521

INFORMED CONSENT PACKAGE

FACTSHEET



OneAquaHealth

PROTECTING URBAN AQUATIC ECOSYSTEMS TO PROMOTE ONE HEALTH

Research site information	
Country/region	
Coordinator	
Partners involved in the pilot	
Other relevant contacts in our research site	

Background

Urban aquatic ecosystems are extremely relevant connectors between people, animals, and plants, making cities more biodiverse and sustainable. Yet, these ecosystems are often confronted with a lack of space, reductions in vegetation, artificialization, and other urbanisation processes. This degradation can lead to numerous negative impacts on humans with regard to emerging pathogens, decreasing disease resistance, climate change impacts and other health concerns in cities.

Objectives

The OneAquaHealth project aims to achieve the following objectives:



Identify LINKS between the HEALTH OF NATURE and AQUATIC ECOSYSTEMS and HUMAN HEALTH



Improve the LEVEL OF INTEGRITY of urban aquatic ecosystems for the maintenance of HUMAN HEALTH and wellbeing, ANIMAL and PLANT HEALTH and the MITIGATION of the RISKS OF DISEASES outbreak.



Determine ENVIRONMENTAL PARAMETERS for predicting DISEASE OUTBREAK RISKS related to aquatic ecosystem degradation, which may constitute EARLY WARNING INDICATORS.



Collect EARTH OBSERVATION DATA to monitoring early warning indicators.



Develop a TOOL that allows the selection of measures to ACT UPON EARLY WARNINGS. Engage stakeholders for RISKS CONTRIBUTING to an EARLY WARNING SYSTEM.

Project Facts

Duration:

2023 to 2026

Programme:

Horizon Europe HORIZON-CL6-2022-GOVERNANCE-01 Research & Innovation Action

Grant ID: 101086521

Coordinator:

University of Coimbra

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NOTE ON USING THIS TEMPLATE

This “Informed Consent Package” is meant to be used as a starting point for specifying correct and complete information for obtaining informed consent for a study involving human subjects in the OneAquaHealth project. At various places, information is highlighted in yellow, indicating that this should be carefully checked, completed, or changed in accordance with the specifics of the study.

Please carefully read and adjust all information in this package, according to the details of your specific study!



Make sure that ALL information is presented to participants in their own native language! Inability to read and understand the language of the informed consent information should be an exclusion criteria for participants.



Please contact the SHINE 2Europe team involved in the OneAquaHealth project in case you have any doubts on how to successfully complete this form, or if you wish for it to be verified upon completion.



Please remove this page before finalizing this Informed Consent Package!

Informed Consent Form

Dear Sir / Madam,

You have been invited to participate in this study which is part of the European project “OneAquaHealth” that aims to improve the sustainability and integrity of freshwater ecosystems in urban environments. By investigating the connection between ecosystem health and human well-being, the project will identify early warning indicators and enhance environmental monitoring with AI-assisted tools. As a result, the project will support decision-makers in finding adequate and timely decisions as well as effective measures to restore aquatic ecosystem health and promote OneHealth.

You will receive detailed information about this study in a personalized way.

This information folder has two parts:

- Part I: General information about the study
- Part II: Informed Consent (to be signed if you agree to participate in the study)

If you do not want to participate, this will not affect your relationship with the institution contacting you in any way, and there will be no negative consequences for you. If you agree to participate, you are also free to leave the study at any time, without the need to provide a reason for your decision. Your choice and your right will always be respected.

The engagement of people in research projects is essential to deliver useful and relevant results. To do so, we require your written consent to cooperate with us. Please carefully read Part I of this information folder before deciding. You can also ask for the clarifications you need and ask any question that does not have a clear and complete answer in this document.

Sign Part II of the information folder only if:

- You fully understood the type and procedure of the study.
- You are willing to give your consent in writing.
- You understand your rights as a participant in this project.

Continued on the next page.

PART I: GENERAL INFORMATION

1. What is the purpose of this study?

The study is part of a European project *OneAquaHealth* which aims to improve the sustainability and integrity of freshwater ecosystems in urban environments. By investigating the connection between ecosystem health and human well-being, the project will identify early warning indicators and enhance environmental monitoring with AI-assisted tools. As a result, the project will support decision-makers in finding adequate and timely decisions as well as effective measures to restore aquatic ecosystem health and promote OneHealth.

2. Who is responsible for the study in [INCLUDE RESEARCH SITE]?

The project is coordinated by the University of Coimbra in Portugal and consists of a consortium of partners from Portugal, France, Norway, Greece, Austria, Spain, Italy, Israel, Belgium, and Switzerland. The co-creation activities are part of a specific “Work Package”, of which [Organisation] is the responsible organisation for these consultation activities developed in [country].

The researcher responsible for the study at [organisation]

Name – [name of contact person]

Contacts – [Phone number] | [e-mail address]

3. How will this study work?

[DESCRIBE STUDY PROTOCOL]

4. What are the benefits of your participation in the study?

By participating in this study, and providing your opinions, you are contributing to the development of a system of services that aims to... [DESCRIBE BENEFITS BASED ON SPECIFIC STUDY]

It is possible that your participation in this study will not directly benefit your health; however, by participating and providing us with your feedback, you will contribute to developing an efficient and practical multifunctional support system. The results of this evaluation will allow us to better define the system to be developed so that the OneAquaHealth system is useful and adequate for you and other citizens.

5. Are there any risks, discomforts or side effects related to your participation in this study?

Since it is a non-evasive study, no risk is predicted. However, if you find any doubt, difficulty, or problem, please contact the researcher responsible for the study in your country immediately.

6. Is there any cost of participating in the study? Is there any financial reimbursement for participants?

There are no costs associated with your participation in or arising from the study, nor will you receive any financial compensation for your collaboration.

7. How will the data collected in this study be treated?

All data will be protected against unauthorised access. The information collected about you will be safely stored by the organisation that conducts the study and all personal data will be deleted at the end of the OAH project in December 2026 (research result data may be kept for five to ten years after the project's end, in accordance with the project's Data Management Plan). The data gathered from the [interview/study/focus group] will be used for analysis and included in the project's deliverables and reports. Unless you have given express consent for the use of your name in part II of this document, your answers will be anonymised. The [interview/study results/focus group outcomes] will be summarised and used as an information source; any recordings of the study will be deleted at the end of the OAH project in December 2026, and only results of the study will be stored for longer. In addition, those responsible for the study will not have access to your date of birth (only your age) and it will not be possible for any other researcher to identify what were your responses, other than the researchers responsible for conducting the [study/interview/focus group]. If the data is shared with other researchers and research institutions that are not part of the consortium, your name will never be included and cannot be identified. Likewise, any publications that may result from this study will not include any personal information that may lead to your identification.

Your participation is planned to last until the finalisation of the Project in December 2026. All members of this study are bound by European data protection standards. If you have any questions about the processing, sharing and storage of your personal data, please contact the project manager or data protection officer of this institution.

8. Early withdrawal of your participation in the study.

You can interrupt your participation at any time without any explanation. The withdrawal will have no negative consequences for you or for the service that [organisation] provides to you.

You may also have access to your data which is collected during the study and make corrections if you find any misunderstanding.

Even after completing the study, you have the right to express your wish that your data be removed and deleted, except for those that have already been published or used in reports that cannot be redeemed or changed. To request the deletion of your data, please contact the researcher in charge of the project.

9. Possibility to discuss other issues.

If you have any questions about the project or about your participation in it, you can contact the project manager at [organisation] now or later.

You can also contact the Coordinator of the project, responsible at the international level – [FILL name, institution, place, email address]. In addition to the researcher responsible for the study and the person in charge of the data processing from [research sites], you have the right to complain to the [FILL country] National Data Protection Commission about the processing of your personal data through [FILL e-mail, telephone].

10. Contacts

- **Researcher at** [organisation]

Name – [fill in]

Contacts - [Phone number] | [e-mail address]

- **Data Protection Officer at** [organisation]

Name - [fill in]

Contacts - [Phone number] | [e-mail address]

- **Responsible researcher at international level of this activity**

Name - [fill in]

Contacts - [Phone number] | [e-mail address]

If you wish to participate in this study, we would like you to complete Part II - Informed Consent Statement and to keep this information folder for future reference.

PART II: INFORMED CONSENT STATEMENT
--

I declare that I have been fully and comprehensively informed of the purpose, meaning and scope of the study, as well as of all possible risks and impacts in my home and in my life.

This information was given to me by _____.

Please tick all appropriate boxes:

	I hereby declare that I am willing to take part in [NAME OF THE STUDY].
	I declare that I have been properly informed about the OneAquaHealth project and I understand the written and verbal explanations.
	I was given proper time to reflect on the participation request; I had the opportunity to make the necessary questions and I received satisfactory answers.
	I authorise audio/video recordings which will only be used for analysing the data from the [study/interview/focus group] and further technical development.
	I know that the data from the [study/interview/focus group] will be analysed and summarised by my interviewer; I will have the right to review this summary before it is shared with the research team for integration in the synthesis report.
	I was informed that the data will only be stored until the end of the OneAquaHealth project in December 2026, after which it will be deleted and that I can access or change/delete it at any time.
	I understand that my name will only be displayed with my express consent.
	I understand I can withdraw my participation at any time, without having to give a reason and will have no penalties because of it.
	I would like to receive more information about the OneAquaHealth project and receive the project newsletter at the following address:

Please, select ONLY ONE option:

	I would like my name to be used as a participant in OneAquaHealth interviews and I understand it can be used in different reports and publications within the scope of this project.
	I do not allow my name to be used.

PARTICIPANT

Name: _____

Date: ____ / ____ / ____

Signature: _____

RESEARCHER

Name: _____

Date: ____ / ____ / ____

Signature: _____

Data protection of participants

By signing this form, I agree with the processing of my personal data and its anonymous transmission possibly also outside the European Union, for research purposes.

Signature of the participant: _____

Date: ____ / ____ / ____

Informed consent statement for parents / legal guardians

I declare that I have been fully and comprehensively informed of the purpose, meaning and scope of the study of the OneAquaHealth Project, the involvement of my child or child for whom I am responsible as well as of all possible risks and impacts in her/his daily life.

This information was given to me by _____.

Please tick all appropriate boxes:

<input type="checkbox"/>	I hereby declare that I give permission for my child to take part in [NAME OF THE STUDY].
<input type="checkbox"/>	I declare that my child and me have been properly informed about the OneAquaHealth project and both understand the written and verbal explanations.
<input type="checkbox"/>	My child and I were given proper time to reflect on the participation request; Both had the opportunity to make the necessary questions and we received satisfactory answers.
<input type="checkbox"/>	I authorise my child's audio/video recordings which will only be used for analysing the data from the [study/interview/focus group] and further technical development.
<input type="checkbox"/>	I know that the data from my child's [study/interview/focus group] will be analysed and summarised by the researcher; My child and me will have the right to review this summary before it is shared with the research team for integration in the synthesis report.
<input type="checkbox"/>	I was informed that my child's data will only be stored until the end of the OneAquaHealth project in December 2026, after which it will be deleted and that I can access or change/delete it at any time.
<input type="checkbox"/>	I understand that my child's name will only be displayed with my express consent.
<input type="checkbox"/>	I understand my child can withdraw her/his participation at any time, without having to give a reason and will have no penalties because of it.
<input type="checkbox"/>	I would like to receive more information about the OneAquaHealth project and receive the project newsletter to the following address:

Please, select ONLY ONE option:

<input type="checkbox"/>	I would like my child's name to be used as a participant in OneAquaHealth interviews and I understand it can be used in different reports and publications within the scope of this project.
<input type="checkbox"/>	I do not allow my child's name to be used.

PARTICIPANT PARENT/GUARDIAN

RESEARCHER

Name of the participant: _____

Name: _____

Name of parent or legal guardian: _____

Date: ____ / ____ / ____

Date: ____ / ____ / ____

Signature: _____

Signature: _____