PROJECT DELIVERABLE REPORT

NAIADES

Greening the economy in line with the sustainable development goals

D10.1 H - Requirement No. 1

Project Title:

A holistic water ecosystem for digitisation of urban water sector

SC5-11-2018

Digital solutions for water: linking the physical and digital world for water solutions

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 820985"

Document Information

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2.0	26/05/2021	CERTH	Revision according to PO comments
2.0	26/05/2021	CERTH	Final version of the deliverable

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1 Summary

This deliverable provides detailed information about the informed consent procedures that will be implemented for the participation of research participants in pilot trials and also for the recruitment procedure. Furthermore, the templates of the informed consent and information sheet that will be used for the participation of people in the pilot trials are provided.

2 Introduction

2.1 Purpose and Scope

This document addresses the ethical issues related to the procedures and criteria that will be implemented to identify/recruit research participants within the NAIADES project. These issues include recruitment of participants to participate in pilot trials, the information which is provided to participants and informed consent forms.

The activities of the NAIADES project are fully aligned to and respect the existing regulations expressed in international texts and codes of practices; in particular the General Data Protection Regulation (GDPR) 2016/679 agreed upon by the European Parliament and Council in April 2016, which repeals the Data Protection Directive 95/46/EC is in force since May 2018 as the primary law regulating how to protect EU citizens' personal data.

The NAIADES project activities shall not entail any risk and burden for the individuals concerned. All the experimental data shall be collected, stored, processed and used following the abovementioned EU Directive and Legislations.

Data acquisition and processing regarding participants involvement will be performed in the context of:

- WP6: Water Consumers Awareness and Behavioural Change Support in T6.2 NAIADES User Profile, T6.3 Personalised nudging engine, T6.4 NAIADES Personalised Water Behavioural Change Application and T6.5 non-ICT public awareness and behavioural change interventions (relevant languages in addition to English: Greek, Dutch, French, German, Italian, Spanish, Hebrew, Italian and other languages as appropriate).
- WP7: Operational and Management tools in T7.1 Implementation of NAIADES Front End Functionalities and Advanced Human-Machine-Interfaces, T7.2 Artificial Intelligence Decision Support System (relevant languages in addition to English: Greek, Dutch, French, German, Italian, Spanish, Hebrew, Italian and other languages as appropriate).
- WP8: Raising Awareness, Standardisation and Exploitation Roadmap in T9.2 Dissemination & Exploitation Strategy & NAIADES Business Plan and T.8.3 (Training workshops and remote training). The above refer to "use of research-related content" generated within WP2, WP3. WP4, WP5, WP6 and WP8 for information and dissemination purposes.
- All other possible activities that may emerge

Regarding ethical and practical issues of their participation, the involved individuals will be properly informed about the NAIADES project concepts and objectives through an appropriate and detailed Information Sheet, in order to have clear view of the concept of the project and the expected participation on their behalf, before asking them to sign an informed consent form that has been produced by the NAIADES Consortium. The Information Sheets will constitute an integral part of the relevant Consent forms. Regarding the processing of the participants' personal data, the involved individuals will be properly informed through a personal data informative text (Annex III).

3 Procedures and criteria for identification/recruitment of NAIADES participants

3.1 Procedures for identification/recruitment

For each research activity, the details of the procedures and criteria to be used will be given to the participants. The protocol for recruiting research participants will involve the following steps:

1. Partners identify appropriate participants within their own network.

2. Partners verify that candidate participants comply with the research criteria (Subsection 3.2 Criteria for identification/recruitment).

3. Participants are provided, through an attachment in their invitation e-mail, with the Personal Data Informative Text (Annex III) which they shall sign and deliver to the project team before the commencement of their participation in the project.

4. Participants will then be provided with the Information Sheet and the Informed Consent Form (Annex I and II), which will be signed by them and countersigned by a member of the project team. Both the Information sheet (Annex I) and the Informed Consent Form (Annex II) will be translated into appropriate languages according to the task to ensure that the data subject has a clear understanding of the documents.

5. When signatures are confirmed, the activity can proceed.

6. Upon completion of the activity, all forms shall be collected by the local NAIADES correspondent (coordinator of the specific activity) in each country.

Participants are able to withdraw from the research activity at any point and it will be made clear to them that participation is voluntary and their data will be safe, through the use of technical and organisational measures, for as long as they are a part of the project (and deleted with no traces if they decide to leave the process, except if they need to be kept by the Data Controller for a specific time period in compliance with regulatory or legal obligations). The experimental data (not personal) collected prior to withdrawal can be used as part of the project.

3.2 Criteria for identification/recruitment

The trials of NAIADES will involve network monitoring data (consumption data, water and wastewater treatment and quality data), social media data and consumer preference data. The selected areas will be defined according to the requirements and specifications derived from task T2.4. A detailed observational plan (as part of the ethics guidelines to be delivered in D1.4: "NAIADES Data Collection & Ethical Plan") will be prepared in strict collaboration with the ethics helpdesk of the NAIADES consortium.

Only adult volunteers will be recruited in each pilot site. The recruitment method and informed consent procedures will be particularly stringent to ensure no coercion (not even soft or indirect) is exerted. The specific criteria for the selection of the volunteer participants are determined by the pilot requirements.

Also specific measures to protect the volunteer participants from a breach of privacy/confidentiality and potential discrimination will be applied, as follows:

- Confidentiality: The personal data of the volunteers participating in the activity will never be revealed in any of the research documents which will be publicised. The personal and contact details of the participants will be accessible strictly to the necessary personnel of NAIADES and shall only be processed for purposes related to the unobstructed execution of the research program and to the fulfilment of NAIADES's legal obligations in regard to the research program. All research data stored and produced during the NAIADES trials will be completely and irreversibly anonymised and will be erased at the completion of the project.

- Right to get more information about the activities of the research: The volunteers can ask any questions about the trials/workshops/focus groups at any time throughout the record. The Designated Researcher (one for each trial/workshop/etc.) will be available to answer their questions, interests or concerns about the project and specific activity. During the process, any volunteer who does not wish to continue to participate in the activity, will have the right to do so, without having to give explanations and without being affected in any way.

- Informed Consent: A detailed informed consent form has been created, fully outlining the scope of the research and its purposes along with the data collected and analysed.

- Personal Data Protection Information: A detailed personal data processing formed has been created, thoroughly informing the data subjects about all the required, under the GDPR, information concerning the processing of their personal data during the research project, their personal data protection rights and how to exercise them.

3.3 Informed Consent in NAIADES Trials

Informed consent is the cornerstone of research ethics. Participation in the research project cannot be performed lawfully without the prior informed consent of the research/data subjects.

As far as the processing for personal data, carried out strictly because that processing is necessary for the successful completion of the research program, the legal basis of the processing is the informed consent. As such, provision of all the relevant information shall be provided to the data subjects, in accordance with article 13 GDPR, through the Personal Data Informative Text document.

As far as informed consent in the context of GDPR is concerned, the notion is explicitly included and defined in the GDPR. Recital 32 of the GDPR states that "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/her". Recital 42 defined informed consent as follows: "For consent to be informed, the data subject should be aware at least of the identity of the controller and the purposes of the processing for which the personal data are intended". Finally, article 7 lists the conditions for consent including the subject's right to withdraw such consent at any time.

By combining the above it is concluded that the basic requirements for a valid legal consent are the following:

- Consent must be freely given.

This entails a real choice by the data subject. Any element of inappropriate pressure turns the consent invalid. According to recital 42, consent should not be regarded as freely given if the data subject has no genuine or free choice or is unable to refuse or withdraw consent without detriment.

- Consent must be specific and informed.

The Commission sets the minimum elements the consent form should include in order for consent to be informed:

o the identity of the data controller and, where applicable, the contact details of the DPO;

o the specific purpose(s) of the processing for which the personal data will be used;

o the subject's rights as guaranteed by the GDPR and the EU Charter of Fundamental Rights, in particular the right to withdraw consent or access their data, the procedures to follow should they wish to do so, and the right to lodge a complaint with a supervisory authority;

o information as to whether data will be shared with or transferred to third parties and for what purposes; and

o how long the data will be retained before they are destroyed.

- Consent must be bound to one or several specified purposes

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.

- Consent must be unambiguous

This means that consent requires either a statement or a clear affirmative act. Consent cannot be implied and must always be given through an opt-in, a declaration or an active motion, so that there is no misunderstanding that the data subject has consented to the particular processing.

3.4 Methodology and guidelines for the delivery of the informed consent

NAIADES trials will require the enrolment of people voluntarily declaring their interest to participate in an experiment. Trials will be accompanied by informed consent forms. The design of the trials observational study will be prepared in strict collaboration with the ethical helpdesk of the NAIADES consortium, in order to respect privacy and ethical issues implied by the data to be collected and analysed.

NAIADES will follow the opinions of various expert committees in the field (e.g. the European group on ethics (EGE) in science and new technologies to the European Commission. In addition, all national legal and ethical requirements of the Member States where the research is performed will be fulfilled. Any data collection and storage involving humans will be strictly held confidential at any time of the research. In particular the consortium will take the appropriate action to ensure:

1. all the test subjects will be informed and given the opportunity to provide their consent to any monitoring and data acquisition process that all the subjects will be strictly volunteers and all test volunteers receive detailed oral information;

2. no data can be collected without the explicit informed consent of people under observation; no person unable to express a free and informed consent for age-related reasons, ongoing medical and / or psychological conditions, mental incapacity, will be enrolled in the study;

3. no personal data will be mixed with the anonymised research data. Personal data will only be stored for project administration and compliance purposes. In addition, data will be scrambled where possible and abstracted in a way that will not affect the final project outcome;

4. no data collected may be sold or used for any different purposes from the NAIADES project;

5. any data, which is not strictly necessary to accomplish the current study, will not be collected; data minimisation policy will be adopted at any level of the project and will be supervised by the ethical/privacy component of the project;

6. any shadow (ancillary) personal data obtained in the course of the observation will be immediately deleted. The collection of data concerning these factors may only be carried out if absolutely necessary for the purposes of a particular inquiry;

7. The consent procedure for the pilot sites will be obtained through a two stage procedure:

   a) On the personal data protection side, the Personal Data Informative Text, will be provided to the data subjects at the same time as their project, trial, workshop invitation, and it shall be signed before their participation in the project.
   b) On the ethics side, initially the designated researcher will orally describe the activity (i.e. pilot trial, workshop, focus group) in which people will be involved in and will also carefully describe the level of privacy infringement that this involves. In case the person wants to exercise his/her right not to know, he/she will be excluded from participating in the project.
   c) Secondly, after a few days, subjects will be required to read and sign an informed consent form that will explain in plain English and in the local language where the research is conducted what has already been orally explained. Informed consent forms in English and in local language will be sent to the European Commission and included in the project protocol.
   d) In addition, subjects will receive in their own language:
      - a commonly understandable written description of the project and its goals;
      - the planned project progress and the related research procedures;

On the other hand, the Ethics Helpdesk (established in WP 1) will scrutinize the research, to guarantee that no undue risk for the user, whether technically, nor related to the breach of privacy, is possible. Thus, the Consortium shall implement the research project in full respect of the legal and ethical national requirements and code of practice. Whenever authorisations have to be obtained from national bodies, those authorisations shall be considered as documents relevant to the project. Copies of all relevant authorisations shall be submitted to the Commission prior to commencement of the relevant part of the research project.

3.5 Specific case of children and/or adults unable to give informed consent

The NAIADES project does not intend to include children, vulnerable people or disabled persons in the research to be conducted. All volunteer participants will sign consent forms. In particular, recruitment criteria will be addressed for each pilot and if employees are to be recruited, specific measures will be in place in order to protect them from a breach of privacy/confidentiality and potential discrimination. The informed consent form which will be used is included in Appendix II.

4 Annex I: Indicative Information Sheet

Information Sheet for the project "A holistic water ecosystem for digitization of urban water sector - NAIADES"

Overview:

You have been invited to take part in the research of the NAIADES project. Before you decide whether you want to participate or not, please read this document carefully. Please ask all the questions you may have so you can be sure of understanding all the processes of the study, as well as the risks and the benefits. The current document may include words that you do not understand. In this case, please ask the contact researcher or any other member of the study to fully explain the meaning of the word or information that you do not understand.

The Project:

The NAIADES project envisions the transformation of urban water management through automated and smarter water resource management and environmental monitoring, achieving a high level of water services for both residential and commercial consumers, exploiting the efficient use of physical and digital components of water ecosystem. NAIADES relies and builds upon various types of big data collected from different water monitoring and control systems in Europe, in order to:

(i) Establish more efficient water consumption in both retail and commercial environments.

(ii) Generate increased confidence of water consumers.

(iii) Measure the water quality in residential buildings, offices and public infrastructures (mall, hospital).

(iv) Assure the safety and reliability through the detection of warning signs in near real time and other monitoring systems.

(v) Enhance public awareness on water consumption and usage savings, and promote user engagement in water conservation activities through personalized persuasive feedback and recommendation services provided to the NAIADES App Users.

NAIADES activities will last 36 months, from the 1st of June 2019 to the 31st May 2022. However, questionnaire information will be available for 60 months from the 1st of June 2019 to the 31st May 2024, in case European Commission performs audits and results evaluation after the definite project deadline.

What is involved in this research?

Your participation will involve taking part in a trial or workshop with a NAIADES researcher(s). This can either be conducted in person or over the telephone, at a time convenient to you. You may be asked to participate in follow-up interviews/discussions where the NAIADES researchers will request more of your feedback.

It is important to remember that there are no right or wrong answers regarding the information you contribute to this research. We are only interested in sharing in your knowledge, honest thoughts, and opinions regarding issues related to the NAIADES project. Your input is very important to this research.

Participation in this activity is completely voluntary and you are free to withdraw at any time without prejudice or penalty. If you wish to withdraw from the activity, simply notify the researcher(s) and your contributions will be confidentially discarded where possible. The experimental data (not personal) collected prior to withdrawal can be used as part of the project.

Will I receive payment for taking part in this activity?

Those participating will not receive payments for taking part.

Risks and Confidentiality of Data

Aside from giving up your time, there are no foreseeable risks associated with participating in this study. Interview recordings will be transcribed but the data will only be seen by members of the research team. It will be stored in a secure area that is not accessible to any individuals other than the research team. Your information will only be used for research purposes. No identifying information will be reported. For detailed information in relation to the processing of your personal data by NAIADES, during the course of this research project, please refer to the "Personal Data Informative Text" document, which has already been provided to you.

How will information that I provide, in relation to the research project, be used?

The information you provide will be used to understand the decision-making challenges that our research is intended to address through the provision of timely, actionable information and tools and techniques. This understanding will be used to refine our project implementation plans.

Ethical Clearance and Contacts

For any issue which arises regarding this study, please inform the designated researcher:

Name

Research Scientist, XXXXX

Address:

Tel:

e-mail:

5 Annex II: Template of Informed Consent Form

Informed Consent Form for the project "A holistic water ecosystem for digitization of urban water sector - NAIADES"

Dear Participant,

Your involvement in this research is highly valued. Please review the information below and sign where required if you agree to participate in this research project.

I, the undersigned, hereby give my consent to take part in the activity carried out by the NAIADES Research Consortium under the following conditions:

1. I have agreed to participate in the project NAIADES (A holistic water ecosystem for digitization of urban water sector) which is conducted under Grant Agreement No. 820985, European Union Horizon 2020 Research and Innovation programme (Topic SC5-1-2018) and the coordinator is the Centre for Research & Technology Hellas (CERTH), Greece, represented by Dr. Athanasios Konstandopoulos.
2. I have been informed about the purposes of the project and the specific activity I will be involved in and all my questions have been answered to my satisfaction.
3. I have been informed that I can address any ethical questions or concerns arising from this research to the designated researcher of the project.
4. My participation in the research will include [describe, e.g. type of research activity, etc.]. Information obtained during the research will be used for [describe].
5. I understand that the research information I provide for this research will be made public to the extent necessary and may be presented in research reports and scientific publications.
6. I understand I will not be personally identified in any reports or publications resulting from the study.
7. I understand that my participation in the project is entirely voluntary and that I am free to withdraw from the study at any time and without having to provide a reason for my withdrawal.
8. I understand I may ask for part of all of the information provided by me to be removed from the study without penalty or explanation.
9. I understand that I will not be paid for my participation.

DATA PROTECTION OFFICER

Yiannis Chalinidis

CENTRE FOR RESEARCH AND TECHNOLOGY HELLAS - CERTH

6th km Harilaou-Thermi Road,

P.O. Box 60361, GR570 01, Thermi, Thessaloniki, Greece

e-mail: dpo@certh.gr, web: http://www.certh.gr

DESIGNATED RESEARCHER

Name

Research Scientist, XXXXX

Address:

Tel:

e-mail:

Done in two copies, of which one is for the NAIADES Research Consortium and one for the participant.

Name and Surname of Participant

……

Date and Place…… ……

Signature……..

Participant Statement of investigator's responsibility:

I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Name and surname of the Researcher

……

Date and Place ……

Signature……..

6 Annex III: Personal Data Informative Text

Personal Data Informative Text for the project "A holistic water ecosystem for digitization of urban water sector - NAIADES"

Dear participant,

You have been invited to take part in the research of the NAIADES project. Because during your participation in the research project some of your personal information might need to be processed, please take some moments to read the following text which contains all the relevant personal data processing information regarding your participation in this research project.

Information for the processing of your personal data during your project participation:

1. The Centre for Research & Technology Hellas (herein CERTH), 6th km Harilaou-Thermi Road., GR570 01, Thermi, Thessaloniki, Greece, acting as the project coordinator for the NAIADES project, shall function as the "Data Controller" for your personal data, which are processed during the research project.
2. This informative text aims to inform you about processing of your personal data, i.e. any information that can identify you or make you identifiable to us or other participants of the project or data recipient. Consequently, this informative text does not contain information in regard to processing of the research data which will be provided by you during your project participation, since all research data will be anonymized and it will not be technically possible for them to be attributed to you or any other project participant, thus they shall not constitute personal data.
3. Your personal data will be collected exclusively by you i. by direct communication (i.e. through e-mail, interview), ii. when you fill in various project participation forms and iii. when you fill in the trial/workshop participation list to confirm your participation in specific trials/workshops.
4. Your personal data is handled with absolute confidentiality, and only the absolutely necessary personnel of CERTH will have access to it. Your data will not be transferred to third countries.
5. Your personal data, collected as mentioned above, will only be processed for the sole purposes of i. optimising the administration of the research project, ii. ensuring the highest possible quality for the research project's results and iii. complying with CERTH's legal and regulatory obligations in relation to the research project.
6. The legal basis of the processing of your personal data by CERTH is that the processing is necessary for the performance of a task carried out in the exercise of official authority vested in the controller.
7. CERTH shall not process any special categories of your personal data for the purposes of the research project.
8. Your data shall be retained by CERTH, for a period of 60 months from the 1st of June 2019 to the 31st May 2024, in case European Commission performs audits and results evaluation after the definite project deadline.
9. You possess the following rights regarding the processing of your personal data:

- Right of access to your data
- Right of rectification of your data
- Right to request the erasure or the restriction of processing of your data
- Right to data portability
- Right to object to the processing of your personal data

If you wish to exercise any of your aforementioned rights, please send a written request to CERTH's designated Data Protection Officer (DPO), whose contact information you can find below:

DATA PROTECTION OFFICER

Yiannis Chalinidis
CENTRE FOR RESEARCH AND TECHNOLOGY HELLAS - CERTH
6th km Harilaou-Thermi Road,
P.O. Box 60361, GR570 01, Thermi, Thessaloniki, Greece
e-mail: dpo@certh.gr, web: http://www.certh.gr

This Signature signifies that I have read and understood the above information

.....
(name/date/place/signature)