SECUREHOSPITALS.EU

RAISING AWARENESS ON CYBERSECURITY IN HOSPITALS ACROSS EUROPE AND BOOSTING TRAINING INITIATIVES DRIVEN BY AN ONLINE INFORMATION HUB

H – Requirement No. 1

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No 826497.

PROJECT DESCRIPTION

Acronym: **SecureHospitals.eu**

Title: **Raising Awareness on Cybersecurity in Hospitals across Europe and Boosting Training Initiatives Driven by an Online Information Hub**

Coordinator: INTERSPREAD GmbH
Reference: 826497
Type: CSA
Program: HORIZON 2020
Theme: eHealth, Cybersecurity
Start: 01. December, 2018
Duration: 26 months
Website: https://project.securehospitals.eu/
E-Mail: office@securehospitals.eu

Consortium: **INTERSPREAD GmbH**, Austria (INSP), Coordinator
Erasmus Universiteit Rotterdam, Netherlands (EUR)
TIMELEX, Belgium (TLX)
Fundacion Privada Hospital Asil de Granollers, Spain (FPHAG)
Cooperativa Sociale COOSS Marche Onlus, Italy (COOSS)
Arbeiter-Samariter-Bund, Austria (SAM)
Johanniter International, Belgium (JOIN)
European Ageing Network, Luxembourg (EAN)

DELIVERABLE DESCRIPTION

Number:	**D7.1**
Title:	**H – Requirement No. 1**
Lead beneficiary:	**INSP**
Work package:	WP7
Dissemination level:	CO
Type	Ethics
Due date:	31.05.2019
Submission date:	30.04.2019

Authors: **Stela Shiroka,** INSP
Yung Shin Van Der Sype, TLX

Contributors: **Peter Leitner,** INSP

Reviewers: **Yung Shin Van Der Sype,** TLX

Acknowledgement: This project has received funding from the European Union's Horizon 2020 Research and Innovation Action under Grant Agreement No 826497.

Disclaimer: The content of this publication is the sole responsibility of the authors, and does not in any way represent the view of the European Commission or its services.

TABLE OF CONTENT

EXECUTIVE SUMMARY

D7.1 ‘H – Requirement No. 1’ is the first WP7. ‘Ethics requirements’ deliverable in the SecureHospitals.eu project.

The goal of this deliverable is to detail how the consortium will address the H-Requirement of the ‘Horizon 2020 Guidance – How to complete your ethics self-assessment’, relating to the involvement of human participants in the project research.

1 Introduction

D7.1 'H – Requirement No. 1' is the first WP7. 'Ethics requirements' deliverable in the SecureHospitals.eu project.

The goal of this deliverable is to detail how the consortium will address the H-Requirement of the 'Horizon 2020 Guidance – How to complete your ethics self-assessment'.[1] This specific Horizon 2020 ethics requirement needs to be met due to the **involvement of human participants in the project research**. SecureHospitals.eu is required to confirm that informed consent will be obtained from participants for their participation in the project research and to keep **informed consent forms** and **information sheets** on file. Moreover, the H-Requirement No. 1 requires to provide details of the **recruitment, inclusion and exclusion criteria** and on the **informed consent procedures**.[2]

The reasoning behind this deliverable is to improve the management and monitoring of the ethics requirements throughout the lifetime of the project, in particular for the data collection during the stakeholder engagement and mobilisation activities (WP2. 'Involve' and WP3. 'Aggregate'), the launch and further development of the Open Awareness and Information Hub (WP2. 'Involve'), the research activities planned in WP4. 'Create', the training activities planned in WP5. 'Boost', and the dissemination activities under WP6. 'Communicate'.

2 Preliminary statement

The SecureHospitals.eu research requires the voluntary involvement of human participants who are able to provide their consent for participation.

SecureHospitals.eu acknowledges that research ethics is given high priority in Horizon 2020-funded research. The consortium will hence comply with applicable national, EU and international legislation on the involvement of research participants and the protection of personal data, as set out in the Description of Action and the Grant Agreement.

3 Identifying and recruiting research participants

3.1 Project activities involving research participants

The SecureHospitals.eu project involves research participants in the context of the following activities:

[1] Horizon 2020 Guidance – How to complete your ethics self-assessment, v6.1, 4 February 2019, http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf.

[2] In addition, the consortium confirms that all participants are able to give their informed consent to participate in the research studies, that they do not belong to any vulnerable groups and that they are themselves not vulnerable individuals (such as minors, patients are healthy volunteers for medical studies).

- Collection of contact information for the purposes of stakeholder engagement and mobilisation in a pan-European knowledge exchange and for further awareness raising activities,
- Research activities via an online survey to understand the general perceptions of healthcare professionals on cybersecurity,
- Qualitative trainer interviews to understand the strengths, weaknesses and potentials of current training approaches on cybersecurity in the healthcare sector,
- Various training activities in the form of a Massive Open Online Course (MOOC), a summer school, and several local workshops and webinars for healthcare professionals with different levels of knowledge on the cybersecurity topic.

3.2 Categories of research participants

The following groups of persons are expected to participate in the SecureHospitals.eu research activities:

1. Healthcare professionals, including doctors, nurses, caregivers, administrative staff handling patient/client data, IT staff and data protection officers working in healthcare institutions, as well as management level professionals,
2. Cybersecurity professionals active as trainers, solutions providers, advisors, etc.

3.3 Recruitment and participation procedures

The research participants included in all above-mentioned activities are volunteers that have been (and will be) identified based on the networks of the project partners, and through publicly available information.

The selection of participants is based on their professional role and function, while encouraging the balanced recruitment of participants from all genders, backgrounds, ages and EU countries.

Participants will either be invited in person or via email, social media and online forum invitations. The research participants are adults who are able to provide their consent to participate in the research and for the processing of their personal data.

Consent forms in the context of participation in online surveys and trainings will be collected and kept in file by the project coordinator (INSP). Consent forms for participation to qualitative interviews or on-site trainings will be asked by the project partner who is responsible for the interview or training. Participants involved in online or on-site trainings will be asked to evaluate the training sessions through questionnaires and evaluation forms online and will be asked to provide consent for such specific purpose by the project coordinator.

3.4 Research safeguards

Participants will be informed about the research study prior to their involvement. At the same stage the informed consent of the research participants will be obtained for their participation in the study as well as for the processing of their personal data. In the information sheet it is expressly stated that participants may withdraw their consent at any time, without having to give any explanation and without being affected in any way.

Participants are able to consult the project's participant's information sheet and data protection notice on the project website.[3] Moreover, participants will be able to ask any questions about the research activities and trials at any time throughout their realisation phase. The partner responsible for the research activity will answer their questions and address their concerns about the research studies or trainings.

Participants of research activities including the survey, interviews and training evaluation forms will not be required to mention their name, affiliation or other information that makes them directly identifiable. In order to analyse the research results and to compare the responses of different participants, a participant number will be assigned to the responses of each participant.

The processing of personal data will be limited to what is strictly necessary to conduct the research studies. The participant responses will be analysed by the consortium and only aggregated research data will be used for scientific publications and presentations at conferences, workshops, and other dissemination purposes.

All personal data will be considered as confidential data by the consortium and will not be shared with or disclosed to third parties external to the consortium without the knowledge of the concerned data subjects, unless the consortium is legally required to do so (e.g. by the European Commission or for law enforcement purposes).

The consortium will continuously apply state of the art technologies and methods for the secure access, storage and transfer of personal data. Personal data will be collected at different research sites with surveys and experiments. The collected data will be stored on a secure server, only accessible by authorised personnel of the consortium partners.

The personal data of research participants will be retained during the lifetime of the project. After the end of the project, the raw research data will be deleted as soon as is contractually allowed, considering the European Commission's retention requirements.

4 Informed consent form and information sheet

4.1 Commitment of SecureHospitals.eu

The informed consent procedure is the process by which participants are fully informed about the research in which they are going to participate.

SecureHospitals.eu will seek informed consent of all research participants. In order to obtain informed consent, the consortium will provide prospective participants sufficient opportunity to consider whether or not to participate and this under circumstances that minimise the possibility of coercion or undue influence. The information given to the participants will be in a language fully understandable to them. No informed consent, whether oral or written, will include any exculpatory language through which the participants are made to waive or appear to waive any of their legal rights, or would release or appear to release the consortium from liability for negligence.

[3] https://project.securehospitals.eu/.

In addition, the information sheets will:

- Identify the responsible person of the research activity and the objectives of the research project and provide contact information for the research participants to ask for more information about the relevant study or training and their participation,
- Describe the aims, methods and implications of the research study or training, specifying the details on the research activity in which the participant will be involved,
- Describe the nature of the participation and any benefits, risks or discomfort that might ensue, including the reason why the participant is invited to take part in the study or training,
- Explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation at any time and without any consequences, and that the participant is not required to answer all questions or to participate in all conversations,
- State how personal data will be collected, processed and protected during the project and either destroyed or reused subsequently and provide information about the confidentiality of the research and trainings.

An example of information sheet and informed consent form has been provided to all SecureHospitals.eu partners. This example explains the main objectives of the project and details on the processing of the information obtained, including information on the actors involved in the processing activity.

The project partners will ask the legal partner of the consortium (TLX) to advise them how to customise the information sheets and consent forms in order to be relevant and appropriate for obtaining participants' consent for a specific project activity.

Copies of all versions of consent forms will be kept on file and consent of specific participants will be logged.

4.2 Examples

The information sheet example and consent form example below illustrate SecureHospitals.eu's approach on these documents.[4]

Please note that the data protection aspects of the information sheet and consent form will be covered by D7.2 'POPD – Requirement No. 2'.

[4] The information sheet and consent form below were used in the context of the survey conducted under T2.2 'Mobilise stakeholders and target groups to identify current public perceptions, experiences and attitudes on cybersecurity'.

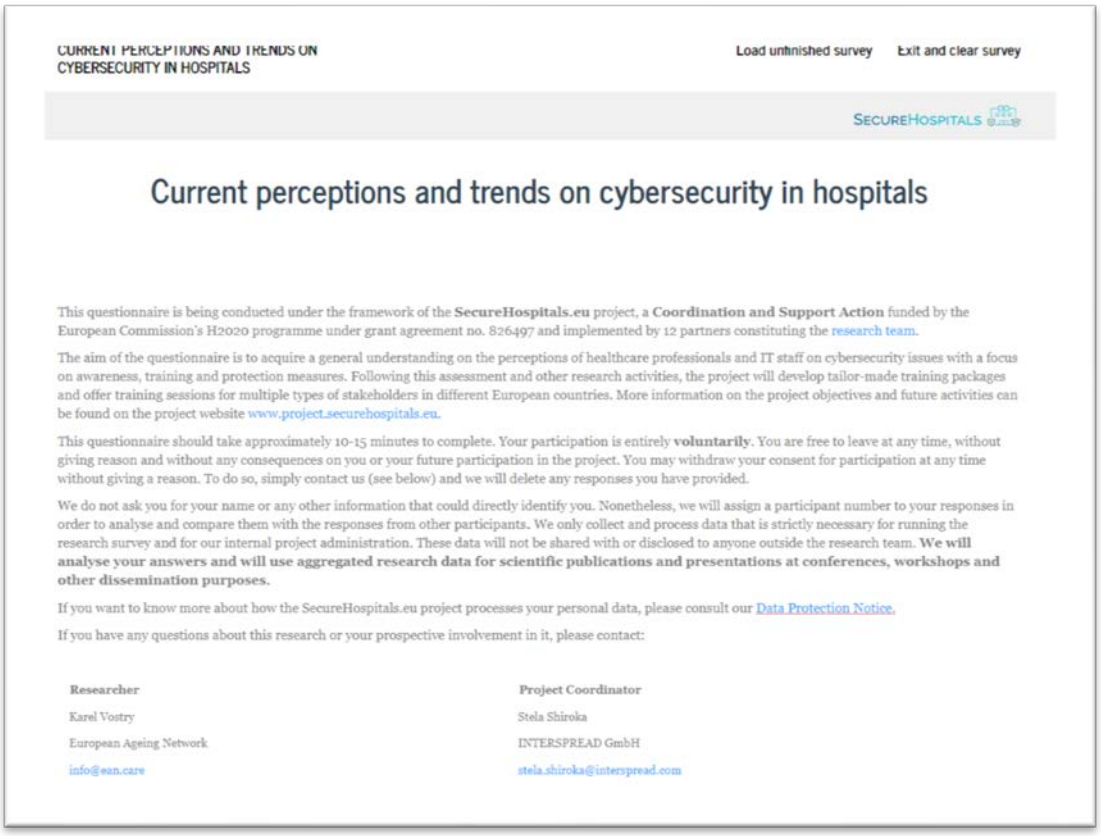

Figure 1. Example information sheet

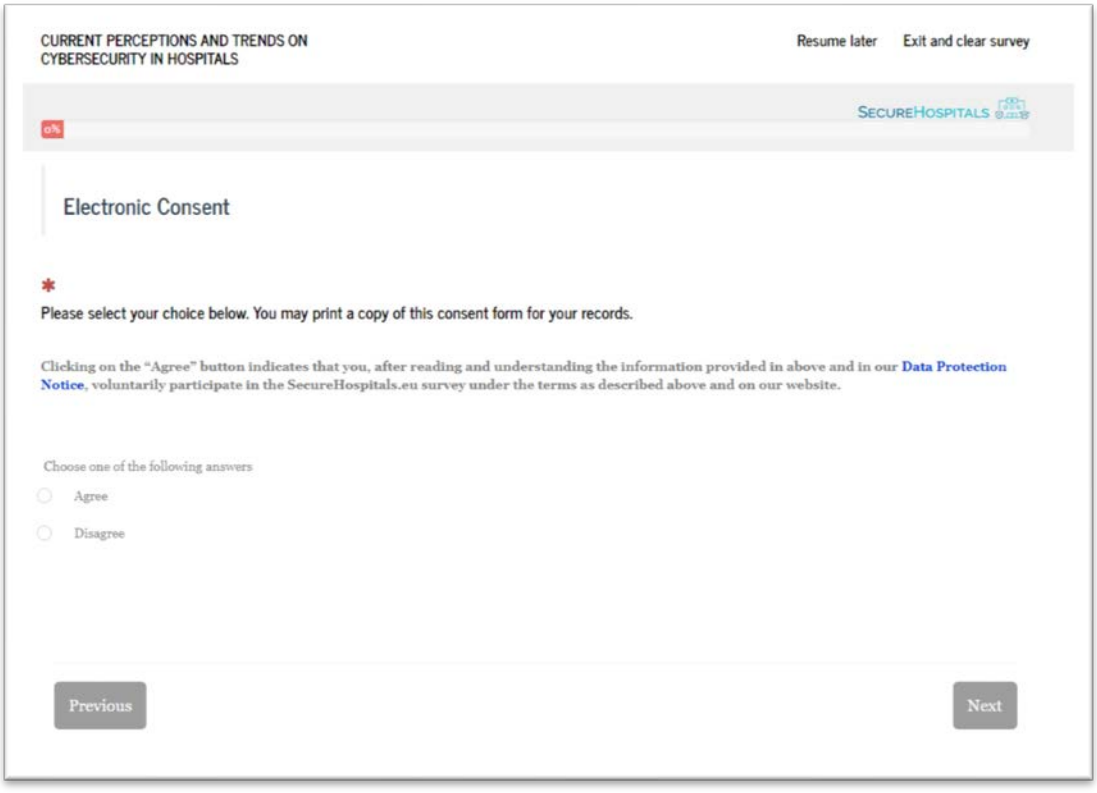

Figure 2. Example consent form

5 Conclusion

The SecureHospitals.eu research involves human participants. Participants are identified and recruited with due care by the consortium partners. All prospective participants will be informed about the research study, and their consent for participation will be obtained, prior to their involvement in the study.

6 References

Websites:

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf