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SoCaTel

**A multi-stakeholder co-creation platform for better access
to Long-Term Care services**

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Ethical and Legal Brief

By Ethics Committee led by GFC and URV, TCD, UTA, FONTYS, FONCE as participants

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AUTHORS

Author	Institution	Contact (e-mail, phone)
Marton Gellen	GFC	marton.gellen@gff-szeged.hu

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Point of Contact	Name: Marton Gellen Partner: GFC Tel: +36 70 312 0078 E-mail: marton.gellen@gff-szeged.hu
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ABBREVIATIONS

ACRONIMS / ABBREVIATIONS	DESCRIPTION
GDPR	General Data Protection Regulation that is “Regulation 2016/679 of the European Council and the European Parliament on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC
SoCaTel	Project <i>SoCaTel A multi-stakeholder co-creation platform for better access to Long-Term Care services</i> (Innovation Action)
AB	Advisory Board
LTC	Long-Term Care
IT	Information technology
EC	European Commission
EU	European Union
GFC	Gál Ferenc College (Hungary)
UTA	University of Tampere (Finland)
FONTYS	Fontys University of Applied Sciences (The Netherlands)
FONCE	Fundación ONCE (Spain)
URV	Rovira i Virgili University (Spain)

1 Introduction to the first *Ethical and Legal Brief*

The SoCaTel project raises sensitive ethical issues, especially as it targets a vulnerable population – that of older people who may be in need of Long-Term Care (LTC) services. The development of the project will involve the collection and storage of personal data deemed to be sensitive. As one of SoCaTel's core values is the protection of its users, their privacy and dignity, the project introduces specific data protection and security procedures and measures that correspond to the Task 2.1 "Ethics and legal observatory" of the WP2 *Ethical Framework*, as specified in the SoCaTel Workplan.

An Ethics Committee, led by GFC and with the participation of URV, TCD, UTA, FONTYS and FONCE, is responsible for a continuous monitoring of all sensitive ethical and legal aspects concerning SoCaTel project (timeframe: M1-M36) and ensure they are properly handled. In order to achieve this goal, Ethics Committee will prepare *Ethical and Legal Briefs* periodically during differing phases of the project implementation. Such documents ought to support project participants regarding their practical activities while fulfilling their project obligations.

However, the first *Ethical and Legal Brief* needs to have a wider scope for many strategic matters, such as the architecture of the co-creation platform which is to be determined at this early stage of the project. Because of these two special characteristics, the current *Ethical and Legal Brief* is necessarily less practical and more theoretical compared to the Ethical and Legal Briefs we expect to have in the future. It focuses mostly – but not exclusively – on the legal novelties of General Data Protection Regulation (GDPR) that is to enter into force 25th of May, 2018. The most critical elements of GDPR from the practical perspective of a scientific research are the management of consent given by data subjects, ensuring that such consent has all its necessary legal elements, and the withdrawal of consent regulated in the new European data protection regime.

Looking into the future, we can predict that the regulations of GDPR are going to be fine-tuned by further EU and national legislations, therefore SoCaTel partners are called on to inform the Ethics Committee if they receive information regarding new national laws affecting the issue of data protection or any other legal issue or requirement pertinent to SoCaTel.

Finally, this document's main purpose is to define the process of ensuring data protection by the SoCaTel Ethics Committee, brakedown into two sub-processes:

1. The process / guidelines of ensuring data protection in the phase of data collecting, during the execution of project's workshops and co-creation sessions (WP1 and WP5).
2. The process / guidelines for ensuring data protection in the phase of data processing and storage, particularly during the design and development of the SoCaTel software/platform (WP3).

2 The mandate of the Ethical Committee of SoCaTel project

Ethical Committee of SoCaTel project issued this *Ethical and Legal Brief* according to its mandate formulated as follows:

“An Ethics Committee led by GFC and with the participation of URV, TCD, UTA, FONTYS and FONCE, will be responsible for monitoring all sensitive ethical and legal aspects and ensure they are properly handled. This committee will take care of recommendations and guidelines established in Deliverable 11.1, which will be followed up, as well as matters regarding data protection in the SoCaTel platform underlined in D2.2. Every remote and physical project meeting will include a session dedicated to the Ethical and Legal Briefs prepared by the Ethics Committee. The briefs will include information about the ethical and legal framework, as well as reports of occurring risks and incidents and how to solve them. The Committee will identify all relevant ethical and legal guidelines at the national and European level and will brief the partners periodically on ethical conduct as well as procedures. This will include not only the process of obtaining informed consent from users and implementing data protection laws, but also best practices with regards to face-to-face interaction during the SoCaTel workshops.”

In the followings, the Ethical Committee puts forth its opinions and recommendations regarding the fulfilment of its mandate.

3 Ethical cases

The Ethics Committee states that institutional Ethical Committees have been involved in the SoCaTel project. No ethical cases or incidents have been reported by participants or clients of SoCaTel until the issuing of this *Ethical and Legal Brief*.

However, to prevent the arising of ethical cases during the project implementation, the SoCaTel members have identified and assessed existing ethical risks and elaborated a related ethics mitigation plan (see the chapter 4).

4 Risks identified

The Ethical Committee, instructed by SoCaTel Advisory Board, has formulated several recommendations designed to eliminate or minimise the impact of the ethical risk occurrences during the phases of 1) recollection of personal information and 2) processing and storage of personal data.

Regarding 1) ensuring data protection in the phase of data collecting, during the execution of project's workshops and co-creation sessions (WP1 and WP5), the Ethics Committee identified the potential risk of not informing properly the participants about their rights while acquiring their consent of taking part in the SoCaTel research. As a mitigation measure, the SoCaTel Ethics Committee proposes the strategy of proper informing of participants about both the research project and their (participants') rights, such as the possibility of leaving the research anytime. The recommendations for best ethical practices are available in chapters 6, 7, 8 and 9 of the present document, together with Annexes I, II, III and IV as templates for data collecting.

In relation to 2) ensuring data protection in the phase of data processing and storage, particularly during the design and development of the SoCaTel software (WP3), the Ethics Committee identified potential risks in the compliance of the IT system that is to be designed and installed in order to support the activities of the SoCaTel (Co-creation platform). Risks occur from the mode of how personal data acquired in the project will be handled.

Elimination of such risks stems from the compliant design of the software architecture with the recommendations on data protection contained in this *Ethical and Legal Brief*. Relevant technical prescriptions and privacy protection requirements as ground rule and guidelines primarily needed for the design and development of the SoCaTel software platform are summarised in the SoCaTel Deliverable 2.2. The D2.2 takes into account the ground-up implementation for GDPR compliancy as an architectural guideline document for the data privacy protection implementation of the SoCaTel software platform and it's underlining automation processes.

Furthermore, the Ethics Committee of SoCaTel has approved "**Data privacy protection requirements** - A technical document summarizing privacy protection requirements feeding into WP3 and WP4" (referred to as: Technical document) as fulfilment of Deliverable 2.2. The Declaration of this Approval is contained in the Annex V of this *Ethical and Legal Brief*.

5 Relevant ethical and legal guidelines

The Ethics Committee identified the following relevant legal framework for the compliant delivery of SoCaTel.

1. Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC with special attention to Art. 19. on ethical principles regarding the conduct of H-2020 projects:

„Ethical principles

1. All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.”

The Ethical Committee found that no prohibited or restricted research fields listed in Art. 19 are affected in the SoCaTel project.

2. Charter of Fundamental Rights of the European Union: SoCaTel participants shall pay special attention to Art. 25 that recognises the rights of old adults. “The Union recognises and respects the **rights of the elderly** to lead a life of **dignity** and independence and to participate in social and cultural life.”
3. The European Convention on Human Rights and its Supplementary Protocols.
4. Regulation 2016/679 of the European Council and the European Parliament on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR).
5. Applying regulations of each affected Member State: SoCaTel recognises that local authorities might have slightly different or varying policies additional to the enlisted legal sources therefore SoCaTel members declare their adherence to legal provisions applied by the Member State of their registration and/or the Member State of their operations.
6. Additionally, this Ethical and Legal Brief contains reference to Unfair Contract Terms Directive (93/13/EEC).
7. European Group on Ethics in Science and New Technologies: Statement on the formulation of a code of conduct for research integrity for projects funded by the European Commission.

6 Recommendations on general ethical issues

6.1 Reporting to the Ethics Committee

Any acts either individual or collective that might be contrary to the norms referred in this *Ethical and Legal Brief* shall be reported to the locally available member of the Ethics Committee. Shall the local member of the Ethics Committee be not available or for any reason excluded from the case, case report shall be filed to the chairperson of the Ethics Committee.

6.2 Preventing conflict of interest

The Ethics Committee promotes the avoidance of potential conflict of interest situations regarding the project partners. In the case of identifying any conflict of interest external to the project, SoCaTel partners shall inform the Ethics Committee without delay. SoCaTel partners shall diminish actual or potential risks of any harm or misconduct in connection with service delivery or in connection with SoCaTel project.

6.3 Measures to prevent discrimination or any harm of human dignity

SoCaTel partners and participating individuals shall call the attention of the Ethics Committee to any discriminatory, ineffective or unjust policies, procedures and practices. Additionally, they shall take all necessary measures – in accordance to local laws and regulations – to expose abuse of power or exclusion of people from services or from decisions that affect them.

7 Recommendations on how to apply new data protection regulations

7.1 Understanding the legal nature of GDPR

EC Regulations have direct effect. However, in the case of the GDPR the situation is slightly more complex. Paragraph 10 of GDPR indicates the following path for its national application: “In order to ensure a consistent and high level of protection of natural persons and to remove the obstacles to flows of personal data within the Union, the level of protection of the rights and freedoms of natural persons with regard to the processing of such data should be equivalent in all Member States. Consistent and homogenous application of the rules for the protection of the fundamental rights and freedoms of natural persons with regard to the processing of personal data should be ensured throughout the Union. Regarding the processing of personal data for compliance with a legal obligation, for the performance of a task carried out in the public interest or in the exercise of official authority vested in the **controller, Member States should be allowed to maintain or introduce national provisions to further specify the application of the rules of this Regulation.** In conjunction with the general and horizontal law on data protection implementing Directive 95/46/EC, Member States have **several sector-specific laws** in areas that need more specific provisions. This Regulation also provides a margin of manoeuvre for Member States to specify its rules, including for the processing of special categories of personal data (‘sensitive data’). To that extent, this Regulation does not exclude Member State law that sets out the circumstances for specific processing situations, including determining more precisely the conditions under which the processing of personal data is lawful.” As such, extensive national legislation is to be expected at all Member States regarding the duties of the controller as well as regarding the content of personal data the latter being at the core of the entire data protection regime.

The Ethics Committee concludes that SoCaTel IT systems and data protection policies shall be designed in a way that they could absorb further legal changes in the upcoming years without major difficulties in the legal or IT management sense.

7.2 Purpose of Processing Personal Data

SoCaTel partners shall always inform the clients on the purpose of their handling personal data. The act of informing clients shall be added to the general protocols.

SoCaTel members, researchers, third parties, subcontractors and volunteers process (handle, collect, manage, store, evaluate, transmit, encrypt or delete) personal data only in order to fulfill the scientific purposes of SoCaTel project. No other personal data is processed in the project.

7.3 Protection of Personal Data in the SoCaTel Project

The data are pseudonymised. The project participants are identified only in the informed consent forms (in paper format) and in an Excel spreadsheet.

7.4 Classification of relevant legal notions

The Ethics Committee collected relevant legal notions regarding the personal data protection regime of GDPR in order to inform SoCaTel participants. Such legal notions are important to understand for everyone who deals with personal data management issues on a regular or on an occasional basis.

7.4.1 Personal Data

According to GDPR: **'personal data'** means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

7.4.2 Data regarding humans

According to the European Group on Ethics in Science and New Technologies: Statement on the formulation of a code of conduct for research integrity for projects funded by the European Commission, "**Data regarding humans:** Where appropriate, researchers, institutions and consortia must define policies relating to the confidentiality of data including assuring the anonymity of any human research subjects, including where necessary the encryption of personal data. Appropriate action must be taken to protect the safety of participants and researchers."

7.4.3 Data concerning health

'Data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.

7.4.4 Sensitive data

General definition of sensitive data is the following: *Any personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life shall only be processed by the prior explicit consent of the data subject.* Such sensitive personal data might be processed without explicit consent of the data subject to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent.

GDPR contains a subcategory within personal data that is different from data regarding health as follows: Personal data which are, **by their nature, particularly sensitive in relation to fundamental rights and freedoms** merit specific protection as the context of their processing could create significant risks to the fundamental rights and freedoms.

The processing of photographs should not systematically be considered to be processing of special categories of personal data as they are covered by the definition of biometric data only when processed through a specific technical means allowing the unique identification or authentication of a natural person. Such personal data should not be processed, unless processing is allowed in specific cases set out in GDPR, taking into account that Member States' law may lay down specific provisions on data protection in order to adapt the application of the rules of GDPR for compliance with a legal obligation or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. In addition to the specific requirements for such processing, the general principles and other rules of GDPR apply, in particular as regards the conditions for lawful processing. It is important to know that certain Member States might have derogations from the general prohibition for processing such special categories of personal data , inter alia, where the data subject gives **his or her explicit consent** or in respect of specific needs in particular where the processing is carried out in the course of legitimate activities by certain associations or foundations the purpose of which is to permit the exercise of fundamental freedoms.

8 Recommendations on how to manage privacy and data protection of all individuals involved in SoCaTel

8.1 Confidentiality

SoCaTel ensures privacy and data protection of all individuals involved in or connected to the project including service recipients and service providers. SoCaTel partners and participants maintain confidentiality by all means regarding any personal data or data of any sensitivity.

8.2 Written note of consent

Personal data are processed with the explicit (written) consent of the data owners, limited by the purpose and by the timeframe determined by the data owners or by their legal representatives. Sensitive data can only be handled or processed under the legal provisions applicable in the country of the service recipient.

8.3 Traceability

SoCaTel manages its activities in a fully traceable and accountable format so that decisions and background information of decisions are archived for any further research or inquiry justified by legally founded purpose.

8.4 Do not transfer personal data across borders

The Ethics Committee recommends that SoCaTel partners should not transfer any personal data abroad. De-personalisation of data gathered throughout SoCaTel research shall be carried out – in line with the principle of subsidiarity – in the country of the data owner.

Cross-border data processing shall only be carried out in a de-personalised form (statistical data) ensuring that the given data cannot be transformed to personal data.

SoCaTel partners shall apply measures to transfer individual data records into statistical data by applying EUROSTAT provisions on creating and processing statistical data. SoCaTel partners use statistical data for scientific purposes, for the betterment of their services and for the individual well-being of service recipients.

The Ethics Committee formulated this recommendation in order to prevent colliding competences of data controllers engaged in SoCaTel project.

8.5 Check-list for best ethical practices of data collecting

Recommendations for researchers to improve SoCaTel research practices through achieving a high-level code of conduct in terms of ethics. The purpose of the following Check-list is to provide practical support for researchers involved in the project. All communication with clients regarding ethical issues should be brief and intelligible for the given individual, should be flexibly adjusted to his or her personal traits.

Best practices for data collection Check-list:

Firstly, researchers should inform the potential participants about the measures taken to protect them, as well as about their rights:

- ✓ Decision about taking or not part in the research will have no consequences on care service receiving

Participation in this study is entirely voluntary. The decision to participate or not will not have any effect on social or health care services that the participant (old adult) receives. In the case of participants' withdrawing consent of data processing, collected data will be erased immediately and will not be used in the study unless already transformed to statistical data.

- ✓ Confidentiality and anonymity are assured

Participation involves attending co-creation workshops and being interviewed. All recorded material, pictures and videos, will be available to both participants and researchers. All these data will be protected (encrypted and/or pseudonymised), assigning an identification number and false name as a measure SoCaTel apply to protect its participants.

No personal data will be disclosed for any third parties. In any written report on the research project, the identity of persons appearing on images or videos can't be revealed without explicit written consent.

Signing the "Consent form template for processing personal data" implies agreeing to participate in the study and be recorded on video. However, the name of the participant will not be recorded and an identification number will be used instead. Any visual information will be processed in accordance to the strict confidentiality of data.

- ✓ Personal data will be erased after five years after payment of the balance (article 18.1 of the Grant Agreement for the project), as indicated in the SoCaTel deliverable D11.2, section 1.5.2.

These procedures are subject to the provisions of Organic Law 15/1999 of 13 December on the Protection of Personal Data. After five years of completing the project, all personal data will be erased. No personal data (images and/or videos) will be used outside research and educational purposes nor in any possible commercial exploitation that derives from it.

- ✓ Participants have the right to withdraw without explaining reasons

Participants can at any time decide to stop the interview. In that case, all collected data will be erased.

Secondly, in order to guarantee a high-level ethical conduct for researchers, it is also advisable to deliver, in the post-interview or post-co-creation session phase, the Letter of Gratitude and organise an event so as to present the SoCaTel research findings and offer feedback/advice to stakeholders, especially old adults:

- ✓ Confidentiality note released by researchers involved in interviews and workshops
- ✓ The Letter of Gratitude delivered

- ✓ An event gathering all participants organized with feedback.

All recommendations offered in chapters 6, 7, 8 and 9 are incorporated in model documents/ templates we enclose in Annexes I, II, III and IV of the *Ethical and Legal Brief*. It is also recommended to deliver these documents in a following order:

1. Information sheet (Annex I)
2. Informed consent (Annex II)
3. Confidentiality note (Annex III)
4. Letter of gratitude (Annex IV)

9 Relevant details of consent as legally applicable act of engagement in SoCaTel research

Ethics Committee – in line with its mandate – formulated the following information on the legal framework contained by GDPR regarding expressing consent for processing personal data. Proposed consent form template is included in the Annex II of this Ethical and Legal Brief. It is important to know that fully hand-written documents might have higher legal value to pre-typed forms according to national laws. In certain cases two legal witnesses would also have to sign such a document in order to ensure full legal credibility of the given document. With regards to such differences in national law, consent form template in Annex II shall be taken as a recommendation.

9.1 Data processing based on consent

Personal data shall be collected only and exclusively based on the consent of the data subject.

The data subject's consent shall mean any freely given specific and informed indication of his or her wishes by which the data subject signifies his or her agreement to personal data relating to him or her being processed.

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.

According to GDPR recital 32, giving consent 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.

9.2 Partial consent

Data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of **SoCaTel** research or parts of **SoCaTel** research project to the extent allowed by the intended purpose. SoCaTel decides upon the written form of giving and registering consent.

9.3 Consent of individuals under guardianship

If the data subject is under legal guardianship – based on the decision of the appropriate authority of the Member State of the residence of the data subject – consent of data processing shall be given by the acting guardian (legal representative). Acting guardian might be a natural person or legal entity. Declaration of consent by a family member shall only be accepted by the controller if such declaration is acknowledged by the law of the Member State. Declaration of consent for data processing given by another person as the data subject himself/herself shall be examined and acknowledged by the local data controller.

9.4 Control rights of data subjects

Each data subject has the right to withdraw his consent at any time of the SoCaTel project. SoCaTel enables deletion of all personal data of data subjects who have withdrawn their consent for any reason. SoCaTel declares that family members without legally acknowledged right of guardianship – including heirs – have no right to withdraw data subject's consent. Deletion of personal information does not affect statistical data generated from personal data prior to the withdrawal of consent.

9.5 Guarantees of freely given consent for data processing

The Ethics Committee supports the dignity of old adults involved in SoCaTel projects. Therefore – in order to ensure that consent is freely given –, consent for personal data processing should not provide a valid legal ground in any case where there is a clear imbalance between the data subject and the controller. Consent is presumed not to be freely given if it does not allow separate consent to be given to different personal data processing operations despite it being appropriate in the individual case, or if the performance of a contract, including the provision of a service, is dependent on the consent despite such consent not being necessary for such performance. Processing should be lawful where it is necessary in the context of a contract or the intention to enter into a contract.

10 The roles of data controllers in SoCaTel

In order to be in line with GDPR, each SoCaTel partner shall appoint a **local data controller** who would be responsible for fulfilling privacy and data protection laws and regulations locally.

A **general data controller** shall be appointed for the entire SoCaTel project who shall have oversight on data transferring, electronic data protection and cryptography protocols used by SoCaTel co-creation platform(s).

Where processing is based on the data subject's consent, the **local data controller** shall be able to demonstrate that the data subject has given written consent to the processing operation. In particular, in the context of a written declaration on another matter, safeguards should ensure that the data subject is aware of that fact and to the extent to which their consent is given. In accordance with Council Directive 93/13/EEC¹ a declaration of **consent pre-formulated by the local data controller shall be provided in an intelligible and easily accessible form, using clear and plain language** and it shall not contain unfair terms. 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. 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.

In Annex V there is the SoCaTel Declaration of Approval which is the Data Protection Declaration by members involved in the pilots and co-creation workshops affirming they fulfill all legal requirements pertaining to EU data protection.

¹ http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#ntr10-L_2016119EN.01000101-E0010

ANNEX I

Information sheet

Nature of the project

The research project for which we request your participation is entitled "A multi-stakeholder co-creation platform for better access to Long-Term Care services- SoCaTel" The goal of the project is to co-create a platform with two interfaces for better access to older and vulnerable adults to Long-Term Care (LTC) services.

The researchers responsible for this study belong to the Universitat Rovira i Virgili (URV) and have the collaboration of Social Services in Vilanova (Spain) along with other partners in Europe from Ireland, Finland, Hungary, the Netherlands and Cyprus.

Procedures

Participation in the study:

The co-creation workshops will consist of having about 8 participants with duration of maximum 2 hours (according to the degree of tiredness and attention of older adults participants). In these sessions, the participants will give their opinions about how the platform will fulfill their needs and improve their quality of life. Once the platform would be finished, it will be tested in another co-creation session to test it. Participation in the study does not imply a risk to the patient and at no time is during physical interventions about his person.

All data collected for the investigation will be stored in digital files, guaranteeing the security of the information collected.

Benefits and risks

The main benefit of the study is the provision of better access to social and care services for old adults. The SoCaTel platform will facilitate end-users' free choice of government and non-government LTC services according to their needs, and will empower citizens' voices and their representatives to champion their causes.

The co-creation sessions will adapt the content and difficulty levels of participants. The platform will improve the quality of life of older adults and their family caregivers.

The participants will also obtain a new experience in citizenship participation and in addressing their needs and to building up more friendly environments. Participation in the study will not involve physical interventions on the person.

Guarantee of voluntary participation

Participation in this study is entirely voluntary. The decision to participate or not, is yours. The fact of accepting or not accepting will not have repercussion in the services that usually might receive by social services or health and care services. Data for withdrawing participants will be erased and will not be used in the study.

Confidentiality and anonymity

Participation involves attending co-creation workshops. During the sessions, no image will be transmitted. In addition, the results of the exhibition will be recorded and will be available to participants and researchers. All data will be encrypted and pseudonymised, assigning an identification number and false name, which corresponds to a single person, applied to protect the person's identity.

In any case, neither the name nor any other personal data will be disclosed in the reports relating to this investigation, or in the reports that are made for third parties.

Signing the consent implies agreeing to participate in the study and be recorded on video. However, the name of the participant will not be recorded and an identification number will be used instead. Any visual information will be processed in accordance with the strict confidentiality of data. In any written report on the investigation or project, the identity of the person on images or videos can't be revealed without his explicit written consent.

These procedures are subject to the provisions of Organic Law 15/1999 of 13 December on the Protection of Personal Data. After completing the project, all data will be erased. No personal data (images and/or videos) will be used outside the research, nor in any possible commercial exploitation that derives from it, since the right to own image is recognised in the Article 18.1 of the Constitution.

If you have further questions or concerns about the project or the implications of participating in it, please do not hesitate to contact the project managers:

Dr. Blanca Deusdad, Principal researcher, e-mail: blanca.deusdad@urv.cat, Tel. +34 977 558358, Mob. +34 686 724 851

ANNEX II

Consent form template for processing personal data

I have been informed in a comprehensible way about these and other aspects of participation in the project (through the information sheet) and I have had the opportunity to ask questions and solve the doubts that I have. I have made the decision to participate knowing that the decision does not affect my therapeutic care in the center and that I can withdraw from the study at any time.

I request my image and voice to be edited in order to be unidentifiable.

I request my data from the co-creation sessions and/or interviews will be not part of the Open Research Data Pilot.

In case the participant is not able to give consent, as legal guardian of the participant, I have been informed and have understood what is expected of his/her participation and what it consists of. All my questions have been resolved and have agreed to his/her participation, voluntarily, in the project.

I request the participant’s image and voice to be edited in order to be unidentifiable.

I request the participant’s data from the co-creation sessions and/or interviews will be not part of the Open Research Data Pilot.

In compliance with article 5 of Organic Law 15/1999, of December 13, on the protection of personal data, I have been informed that the personal data I provide will be incorporated and treated in the project’s search file SoCaTel. I have been informed that the person in charge of this file is the manager of the URV, with domicile in Tarragona, Carrer del Escorxador, neither that I have the right to access my data or those of my representative, to rectify - and, if applicable, to cancel them and to oppose their treatment, under the conditions provided for in current legislation. To exercise these rights, you must send a letter or form to the Department of Anthropology, Philosophy and Social Work at the URV, Av. Catalunya, 35, 43002 Tarragona, or the electronic register of the URV (<https://seuelectronica.urv.cat/registre.html>).

I freely and voluntarily give my consent so that the person of whom I am a legal guardian participates in the project. And that is why I explicitly authorise it in this consent form.

Location and date in which the informed consent is signed:

	Name	Date	Signature
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Participant			
Legal guardian			

Name of researcher:

Date:

Site and Declaration of the investigator: I have explained the nature and purpose of this investigation and the possible risks for the participants. I have responded to the interviewer's questions. I will send the parents or legal guardians of the participant a copy of this consent.

ANNEX III

Confidentiality Note

This confidentiality note is given to ensure the fulfillment of privacy and data protection requirements in SoCaTel project.

I hereby declare that all information and personal data I have acquired by participating in or contributing to SoCaTel project are of confidential, personal or proprietary nature.

Therefore, I agree to maintain the absolute confidentiality of personal, confidential and proprietary information in recognition of the privacy and proprietary rights of data owners at all times. Furthermore, I commit myself to comply with all privacy laws and regulations, which apply to the collection, use and disclosure of personal information. Should I notice any fraud or misconduct regarding handling personal data or other information of confidential nature in the SoCaTel project, I immediately report it to the body or authority of corresponding legal competence.

..... Signature

ANNEX IV

Letter of gratitude

Dear Contributor,

I would like to express my gratitude for your contribution in SoCaTel project! SoCaTel is an innovative research project, funded by the European Commission, dedicated to find innovative ways to create better services in old adult care.

Should you have any comments or suggestions regarding the execution of the research, please let me know. I honestly hope to work with you again.

Best regards,

Dra. Blanca Deusdad Ayala
Senior Lecturer and coordinator of SoCaTel project
Department of Anthropology, Philosophy and Social Work
Rovira i Virgili University
Avinguda Catalunya, 35
43002 – Tarragona

A/e: blanca.deusdad@urv.cat
Tel. +34 977 558358

ANNEX V

Declaration of Approval

The Ethics Committee of SoCaTel hereby declares the approval of “**Data privacy protection requirements** - A technical document summarising privacy protection requirements feeding into WP3 and WP4” (referred to as: Technical document) as fulfilment of Deliverable 2.2.

Conclusion of the revision process

The process of approval contained the negotiation of minor corrections to the document of which the following was affecting the content.

The Ethics Committee expressed disagreement that consent for personal data processing currently could be lawfully given by ticking a box electronically. The Ethics Committee is aware that recital (32) of GDPR contains this possibility but not as a current norm, rather as a policy aim. Furthermore, SoCaTel partners always adhere to local regulations that are – in their current form – based on Directive 95/46/EC that demanded written expression of consent as legal basis for fully lawful conduct of personal data processing. The necessary modifications proposed by the Ethics Committee were carried out in the Technical document.

Recommendation

The Ethics Committee expresses its expectation that the entering into force of GDPR in May, 2018 is to generate further legislative novelties by the Member States. GDPR itself expresses the necessity of further development of national laws, especially regarding the competences of data controllers in data processing activities. This requirement paves the way for further modifications of national laws that are probable to affect the operations of SoCaTel partners in the duration of the project. Therefore, the Ethics Committee recommends that operational data protection requirements shall be formulated at a feasible level of flexibility in order to offer latitude to SoCaTel partners to fulfil GDPR requirements as well as national regulations even in the phase of occasional divergences.