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Privacy and Ethics guidelines for experimental validation and data collection

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1	AP-HP	26/02/2020	Structure and detailed outline
2	AP-HP	20/03/2020	Context and overview of ethical issues
3	AP-HP	19/04/2020	First draft with full treatment of EC ethics checklist
4	AP-HP	28/04/2020	Second Draft integrating INRIA comments
5	AP-HP	29/04/2020	Third Draft integrating additional comments, annexes and bibliography
6	INRIA	30/04/2020	Final draft with reviewer comments

APPROVALS

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1 ABOUT THIS DOCUMENT

1.1 Role in the project

This document is the deliverable D 10.3. It contains a first iteration of the Ethics and Privacy guidelines and procedures for data collection and experimentation in SPRING that will be completed with technical documents, specifications, as well as with the final response from ethical review bodies that were or will be solicited in 2020. It is the first outcome of WP10, T10.1: Privacy and Ethics protection, as required by the project's Grant Agreement number 871245 and detailed in our Detailed Work Plan (D9.3). This document will be scrutinized in close synergy with the project quality plan (Deliverable D9.2).

The deliverable defines the ethical and legal policy of the consortium throughout the project. It identifies the challenges related to the project, regarding ethics and law, and provides a set of guidelines to address them. This document is the main reference for all the work conducted by SPRING members. Since it emphasizes issues related to the management (collection, transfer and processing) of personal data from vulnerable and elderly participants in eldercare setting, the deliverable particularly valuable for partners involved in WP1 and WP7.

- INRIA as the project's co-controller
- APHP who will conduct the experimentation on the ground and who stands as the ethic guarantor of the project
- ERM who will monitor data management

This document may also be reused for future projects dealing with the use of social robotics in healthcare settings, or any other environment alike.

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2 SPRING AND SOCIAL ROBOT ETHICS

The main objective of SPRING is to develop a Socially Assistive Robot (SAR) able to interact simultaneously with multiple persons and perform open-domain dialogues in cluttered environments. Although most of the preliminary work will be done in simulated environments, in partners' laboratories (universities, living lab), the main experiments (WP1 & 7) will take place at the Day Care Hospital (DCH) of Broca Hospital, a public geriatric care facility located in Paris (France).

The SPRING project robot will interact with actual users (elderly patients and family members) and professionals (health and social car, administrative, etc.) from the DCH, during the open hours of the institution. As such, the SPRING project raises many ethical issues. Some are related to the overall development of robotic technology in western societies, while others are more specific to the setting of Broca's DCH.

2.1 Future of Socially Assistive Robots

First, SAR may be understood as "*embodied forms of semi-independent or independent technology*" (Vandemeulebroucke, Casterlé et Gastmans 2018, p. 15), « *encompassing all robotic systems capable of providing assistance to the user by means of social interaction* » (Pino et al. 2015, p. 2). They are hybrid entities combining features of Socially Interactive Robots (SIR)[1] with those of Assistance Robots (AR)[2]. SARs covers a wide range of robots, with different shapes and functionalities. Although researchers sometimes struggle to define accurate classification to differentiate SARs from each other (Mordoch et al. 2013; Kachouie et al. 2014, p. 370), SPRING's robot may be labelled as a human-like robot.

In the last decades, the use of SARs has risen in developed countries. Today, these can be seen in various public spaces (Mubin et al. 2018), like shopping malls (Chen et al. 2015; De Gauquier et al. 2018; Niemelä et al. 2019), hotel reception desks (Zalama et al. 2014) or museums (Faber et al. 2009). Hence, the use of SAR may concern different users, from random pedestrians (« Do You Need Help? A Robot Providing Information to People Who Behave Atypically - IEEE Journals & Magazine »), to students (Chang et al. 2010), children with autism (Robins et Dautenhahn 2007) or adults living in eldercare facilities (Rouaix et al. 2017; Pino et al. 2015; Demange et al. 2018).

The spread of the use of social robots in some societies raises many questions. On the one hand, it challenges their current legal frameworks (Bensoussan et Bensoussan 2015; Nevejans 2018), their work organization (Noble 2016) and the ethical or philosophical beliefs of their citizens (Złotowski et al. 2015; Coiffet 2018; Vandemeulebroucke, Dierckx de Casterlé et Gastmans 2018). On the other hand, SAR provide new opportunities. For instance, some expect SARs to ease the workload of manual workers (Parks 2010), while others consider the use of SARs as a possible way to tackle issues related to population ageing (Broekens, Heerink et Rosendal 2009; Robinson, MacDonald et Broadbent 2014; Chau et Osborne 2017).

[1] SIRs are "robots for which social interaction plays a key role"(Fong et al. 2018, p. 145)

[2] ARs "give aid or support to a human user" (Bemelmans et al. 2012, p. 115) and provide physical support to caregivers in their daily task.

2.2 Future of Socially Assistive Robot in eldercare

Accordingly, the use of robots in healthcare settings has increased these last few years. Today, SARs are able to perform a large spectrum of tasks. They can deliver food, medicines or samples, or perform complex cognitive therapies (Robins et Dautenhahn 2007), or assist persons whose critical body functions are impaired (Bloss 2011; DiGiose 2013; Gombolay et al. 2018; Lonner, Zangrilli et Sundeep 2019; Milner et rice 2019). In eldercare institutions, many papers have reported on the use of SARs since the late 2000's. Robots have been involved in numerous applications, like cognitive rehabilitation, non-pharmacological interventions (Bemelmans et al. 2012; Mordoch et al. 2013; Pino et al. 2015; Jøranson et al. 2016; Petersen et al. 2017; Demange et al. 2018), or entertainment and companionship to institutionalized adults (Rouaix et al. 2017).

The use of SARs in healthcare seems to hold much potential. In both healthcare and eldercare, some expect SARs to help reduce work overload (Parks 2010; Fauth et Gibbons 2014; Song et Oh 2015), providing support in clerical, logistic or transportation tasks (Ozkil et al. 2009; Lonner, Zangrilli et Sundeep 2019, p. 237). The use of SARs may help to take up the rising number of older adults with cognitive disorders in institutions (Prince et al. 2016; Livingston et al. 2017). Some even argue that Socially Assistive Robots may foster the "humanization of care", allowing professionals to focus on most important elements of the care (Chui, Manyika et Miremadi 2016; Lonner, Zangrilli et Sundeep 2019, p. 233).

2.3 Ethical implications of the use of SAR

Nevertheless, many legal and ethical questions are yet to be addressed. First, SARs may challenge the current legal framework of societies where they operate. Like many other digital devices, SARs may collect data, through the devices they embedded, to enhance their performance. Although national and supranational legislation have adapted to ensure the privacy of their citizen (e.g.: In the European Union, each national legislation was modified to suit the General Data Protection Regulation, passed in 2016 and enforced from 2018), some grey areas remain about the use of personal data. SARs also raise new questions about their responsibilities before the law (Godin 2018; Nevejans 2018) (Bensoussan et Bensoussan 2015).

The spread of social robots in societies also sparks debates about the place of robots in human environments. Some are very practical, and address the use of robots in work environments and their possible effects (Noble 2016). Others works take a philosophical angle to question the evolution of boundaries between human and robots, as the rise of robots seems to blur them (Coiffet 2018; Vandemeulebroucke, Dierckx de Casterlé et Gastmans 2018). Although some of these issues were already identified long before the actual creation of robots (Jarrige 2017), SARs' presence is a fairly new phenomenon that has yet to be addressed.

In healthcare settings, the use of SAR represents specific challenges. Their current technical limitations may generate in some cases additional workload for teams operating these robots (Gombolay 2016). Today's SAR hardy operate autonomously in dense indoor environments, as they often fail to locate themselves with accuracy (Taira et al. 2018; Lynen et al. 2019). Despite significant progress, recognition technologies, to understand the content of audio and visual data, still need improvement (Duta et al. 2017; Du, Wang et Qiao 2018; Fan et al. 2018; Vincent, Virtanen et Gannot (eds.) 2018; Girin, Gannot et Li 2019). As such, current SARs cannot deliver satisfactory interactions in noisy environments. They also have limited abilities to interact with several individuals at once, to identify their needs or to provide

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relevant information. Furthermore, SARs cannot recognize behaviors (e.g. facial expressions, hand- and body gestures, head- and eye gaze) or group behaviors (e.g. who looks at whom, who speaks). They do not have the ability to take non-verbal social signals into account while being engaged in spoken dialogue and they cannot connect the dialogue with the persons and objects that are physically present in their surroundings. As such, the ability of SARs to provide an spontaneous and useful assistance to patients or staff members, or to engage in any convincing dialogue is nowadays limited. Therefore, the opportunity to introduce today's SARs in healthcare can be discussed not only from a technical point of view, but also from an ethical perspective.

In eldercare settings, the use of SARs brings also specific questions. Studies have shown the importance of design to foster the acceptance of social robots among older adults (Flandorfer 2012; Wu et al. 2014). Designers need to meet elderly users' expectations, especially those with low digital literacy. Part of the users in geriatric institutions are expected to be vulnerable. A significant number of them may suffer from cognitive impairment (Prince et al. 2016; Livingston et al. 2017) and may identify the robot as a living creature. It raises the issue of deception and manipulation, especially for human-like and animal-like robots (Zawieska 2015; Arkin 2018; van Maris et al. 2020). The clinical profiles of the users, and health related information require to carefully consider privacy issues described above (e.g. the robot may collect sensitive data related to a medical condition of a person). Finally, the use of social robots in geriatric institutions also encourage ethical discussions about the future of the relationship between care providers and patients. For the former, the direct implication of the professional has sometimes been the core component of their work ethics (Billaud et Xing 2016; Guérin 2016; Ravon et Vidal-Naquet 2016). For the latter, the use of SAR may as well help alleviate loneliness that patients often experience, as it may contribute to dehumanizing their daily life in institutions (Zardiashvili et Fosch-Villaronga 2020).

Ethical challenges of the use of SARs in geriatric settings can be summarized as follows:

- Ensure the privacy of users regarding personal data's management and boundaries between private and public.
- Manage to mitigate the psychological effect of the robot on vulnerable patients.

Limit the negative impacts, both organizational and psychological, of the robot's presence on the care professional's daily work.

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3 SPRING ETHICS FRAMEWORK

3.1 Introduction

The main objective of SPRING is to develop a socially assistive robot able to perform in noisy and crowded environments. Eventually, SPRING's robot will provide daily assistance and entertainment in geriatric settings. This project is on the forefront of healthcare and technological innovation and, although the risk for participants is low from a medical point of view, it raises significant ethical issues regarding fairness, dignity and privacy. AP-HP, as the ethics guarantor for the project, thus set up a comprehensive strategy for the consortium to protect participants rights (such as their right to decline to participate without any consequences), and to mitigate the adverse effects that the experiments may generate (for example, make sure that they do not impact the quality of routine care).

The following general principles will guide the actions of the consortium regarding these critical issues:

- SPRING members will ensure that each experiment is conducted in accordance with the ethical policy defined in this document, under the supervision of the relevant ethical committees that have been identified.
- Participants will be recruited with respect to their ability to give informed consent. The investigators will assist all the participants, provide all the necessary information, and ensure that their interest always prevails.
- SPRING will comply fully with GDPR requirements for the matter of collection, storage, transfer and processing of personal data. Adequate technical and organizational measures will be implemented to the rights of participants.
- The consortium, as a whole, intends to apply the guidelines of Horizon 2020, specifically on the matter of « Health, demographic change and well-being » and « inclusive, innovative and reflective societies » (*Horizon 2020 in brief* 2014, p. 11)

All along the project, experiments will be conducted to collect data used to build, enhance and evaluate the capabilities of the robot, or some of its modules. Most importantly, the robot must analyse the behaviour and understand the intentions of humans around it to respond accordingly. This implies that human subjects must be involved in many of these experiments, at different stages of the project. The first experiments will be conducted in each partners' laboratory and will involve volunteers with various socio-demographic profiles (students, researchers, volunteers) but no patients or vulnerable subjects. They will serve to create and validate the first versions of the different modules of the robot, as well as the first fully integrated prototype before the main experiment begins.

The main experiment will take place in Broca's DCH, involving actual users of the DCH (patients, caregivers, professionals). Although individuals with severe cognitive impairment will not be included in the experimentation, a significant portion of the participants is expected to suffer from mild and moderate cognitive declines. Hence, the project raises significant concerns about the consent, privacy and dignity of vulnerable participants, and the collection and the management of their personal data.

As such, SPRING Consortium commits to:

- Ensure the right of the participants to be informed and freely consent or decline to participate, and protect their dignity and access to proper care regardless of the attitude towards the experimentation.

- Adapt the study design of the experimentation to ensure maximal privacy of the participants, as well as the full privacy of those who do not wish to participate.
- Ensure to modulate the course of the experiments according to the vulnerability of the participants
- Minimize the amount of data collected and anonymize or pseudonymize this data whenever possible
- Setup secure storage and transfer protocols for the personal data collected

Sections 3.2 covers the ethical strategy followed by the consortium's partners besides AP-HP, for the "pre-experiments" (e.g. experiments done independently by each partner before actual real-world experiments in the DCH). Specific attention will be paid to the main experiment, covered in section 3.3, as it raises the most significant ethical issues.

3.2 SPRING ethical strategy for partners besides AP-HP

To develop their systems before the main experiment, some of SPRING's members will conduct pre-experiments on their sites, namely INRIA, UNITN, HWU and BIU, which will work to develop the modules that the socially assistive robot will embody. CVUT, ERM and PAL Robotics, on the other hand, will not conduct any pre-experiment.

Following the Kickoff of the project, AP-HP, which stands as the ethics guarantor of the project, asked partners who intend to conduct experiments to specify their ethical strategy. Accordingly, they provided details about their testing procedures and the type of people that they will involve. Partners also self-assessed the ethical issues that these pre-experiments may raise and the appropriate measures to put in place to address them and comply with GDPR's framework.

All partners were asked to provide information about the persons they appointed locally to ensure their compliance with SPRING's ethics policy (Person in charge of ethics on site) and personal data policy (Data Protection Officer), as well as their national data privacy controlling bodies and relevant ethical committee, from which they will seek approval for their experiments.

All the documents of approval issued by these bodies and authorities will be collected by AP-HP and appended to the upcoming deliverables, along with the approval of the *Comité de Protection des Personnes (CPP)* regarding the main experimentation conducted at the DCH.

The following subsections give more details about each partner's tasks (3.2.1) and ethical strategy (3.2.2.). The first one indicates the testing procedures on each site while the second outlines the ethical issues that the partners identified, the measures they will take to address them and the relevant national or local bodies and authorities regarding ethics and data protection. All this information is also available in Annex 1 in a standalone format for commodity.

3.2.1 Partner and task descriptions

The pre-experiments that will be conducted by INRIA, UNITN, HWU and BIU aim to develop the software modules of the Socially Assistive Robot ARI that will perceive, analyze and respond to the robot's environment, in particular for behavior analysis of and interaction with humans. The pre-experiments are necessary from a practical point of view, as they allow for easier, more agile development as they are performed by each partner on its own test sites.

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They also serve data minimization objectives, as they will allow partners to enhance their modules in the beginning of the project without using more sensitive data collected in the DCH.

All partners described their testing procedure and the type of people involved as follows:

INRIA, UNITN and BIU will train their AI with existing online databases of audio and visual content and data collected in a neutral experimental context (e.g. not simulating a healthcare or other specific environment) with healthy volunteers with no subordinate relationship with the PI or ethics local contacts. Some of said volunteers may be students from their respective institutions.

HWU will first use publicly available data sets to train the conversational AI. It will then deploy the prototype systems in series of data collection experiments. Participants will interact with the systems on the basis of the use-cases defined in the proposal. These will involve human subjects, students and researchers from the University laboratory in a first phase, and residents and professionals from local elder care facilities in a second phase.

3.2.2 **Partners' ethics strategy**

The partners who will conduct pre-experimental work on their site also self-assessed the ethical issues related to their work. They will define measures to address them accordingly. They will seek advice and approval from the relevant local and national persons, bodies and authorities regarding the enforcement of the project's ethic policy, the protection of personal data and overall compliance with GDPR requirements. Below we specify, for each partner:

- The person in charge of ethics on their site, who is the local person appointed by each partner to ensure the conformity of their activities with SPRING's ethical policy. When necessary, this person also manages the application process to get approval from local committees, bodies or authorities.
- The Data protection Officer, who is the person appointed by each partner to implement and oversee the data protection strategy of the institution and its enforcement all along the project. The DPO also ensures the compliance of the institution with the applicable data protection rules (European Data Protection Supervisor 2017).
- The relevant ethics committees for their local experiment, which are the bodies that provide advice regarding the planned research and assess whether it is compatible with the ethical framework defined by the committee itself or any other local, national or supranational institution.
- The relevant national data privacy controlling body, which is the body in charge of law enforcement for matters related to data privacy at the national level.

All of SPRING partners provided the corresponding information as follows :

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INRIA	
Country	France
Person in charge of Ethics on Site	- Xavier Alameda-Pineda (PI) - Marie Lorphelin (Local COERLE contact) - Cédric Lauradoux (Local COERLE contact) - Sylvain Petitjean (National COERLE contact)
Data Protection Officer	Anne Combe
Reference ethics committee for your local experiment	COERLE (Inria's Operational Committee for the assesment of
National data privacy controlling body	CNIL (Commission Nationale Informatique et Libertés)
Ethical issues	- The use of existing databases. - The collection of personal data (video and sound) - The physical interactions between the robot and researchers / participants - The psychological influence on participants (limited because no direct interaction with the robot)"
Ethical procedures to perform	- Databases will be checked for reducing the chance of ethical issues and conflicts - Project will be submitted to COERLE for review and authorisation. COERLE will verify that there is no risk of injury to researchers and participants in their interactions with the robot used for the experiment. Information on the experiment as well as consent form will be produced in accordance with the EU recommendations
Compliance with regulations for the protection of personal data (GDPR)	- All existing databases used for the experiments will be checked. - For experiments involving human participants, the participants will sign a consent form providing them with sufficiently detailed information on the experiment so that they can make an informed, voluntary and rational decision to participate - The data collection will be declared to Inria's DPO and the local chief information officer who will both verify that the data collection complies with GDPR.

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UNITN	
Country	Italy
Person in charge of Ethic on Site	Elisa Ricci (PI)
Data Protection Officer	Avv. Fiorenzo Tomaselli
Reference ethics committee for your local experiment	- Human Research Ethics Committee of University of Trento https://www.unitn.it/en/ateneo/1755/human-research-ethics-committee
National data privacy controlling body	Garante per la protezione dei dati personali
Ethical issues	- The use of existing databases. - The collection of personal data (video and sound) - The physical interactions between the robot and researchers / participants - The psychological influence on participants (limited because no direct interaction with the robot)"
Ethical procedures to perform	- Databases will be checked for reducing the chance of ethical issues and conflicts - Submission of research proposals to the Ethics committee (IRB) as required.
Compliance with regulations for the protection of personal data (GDPR)	- All existing databases used for the experiments will be checked - For experiment involving human participants, the participants will sign a consent form providing them with sufficiently detailed information on the experiment so that they can make an informed, voluntary and rational decision to participate. They will also sign a document describing GDPR data treatment regulations.

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HWU	
Country	Scotland
Person in charge of Ethic on Site	Oliver Lemon
Data Protection Officer	Heriot Watt Heritage and Information Governance hig@hw.ac.uk
Reference ethics committee for your local experiment	School of Mathematical and Computing Sciences Ethics Committee, University of Heriot Watt
National data privacy controlling body	Information Commissioner's Office
Ethical issues	- Data collected will include audio and video from which participants are potentially identifiable. Third- party Automated Speech Recognition will be employed, therefore the vendor selected must have GDPR-compliant processes. - Residents in care homes are a vulnerable group; some may lack capacity and be under Power of Attorney guardianship. Special care must be taken with these users to ensure that either they are able to give informed consent to participate in the studies, or such consent is obtained from their legally representative proxy. - Where external databases are used AI for training, it must be confirmed these can be freely used for the project.
Ethical procedures to perform	- Submission of research proposals to the Ethics committee
Compliance with regulations for the protection of personal data (GDPR)	- HW will assess the need for a Data Protection Impact Assessment as part of the University's Ethical Approval Process. - In compliance with GDPR, all data collection will be on the basis of informed consent; all participants will sign an informed consent form prior to taking in part in experiments. - All data will be pseudoanonymised, stored on a firewall-protected University server and accessed only by staff on the project.

BIU	
Country	Israel
Person in charge of Ethic on Site	- Sharon Gannot (PI) - Alon Nusbaum (Person in charge pf ethics)
Data Protection Officer	- Alon Nusbaum
Reference ethics committee for your local experiment	- Instiutional Review Board, Human Trials commision (headed by Pr. Yadid Gal)
National data privacy controlling body	- Privacy Protection Authority
Ethical issues	- The use of existing databases - The collection of personal data (mainly audio) - The physical interactions between robot and researchers/participants - Psychological influence on participants is not expected, as the sentences will be neutral and non-personal. No physical risk from the robot is expected.
Ethical procedures to perform	- Databases will be checked for reducing the chance of ethical issues and conflicts - Submission of research proposals to the Ethics committee (IRB) as required.
Compliance with regulations for the protection of personal data (GDPR)	- The GDPR compliance of all existing databases used for the experiments will be checked - For experiment involving human participants, the participants will sign a consent form providing them with sufficiently detailed information on the experiment so that they can make an informed, voluntary and rational decision to participate.

Each partner will submit their own research protocol to their local ethic comities for approval. Proof of approval will be appended to the upcoming deliverables.

3.3 SPRING Ethical Strategy for AP-HP

The main experiments will take place in the waiting room of Broca's hospital, under the supervision of AP-HP professionals. The experiments conducted in Broca hospital differ from those conducted by other partners: while the latter take place in simulated environment, and involve healthy volunteers, the former include patients, caregivers and professional from the Day Care Hospital of Broca Hospital (DCH), who will interact with the robot during or in between standard care sessions. While highly valuable for the consortium, these experiments also raise legitimate concerns about their ethical implications.

DCHs are outpatient facilities which "offer health care to individuals who require service but are able to return to their homes overnight"[3]. In the case of Broca's DCH, the patients are elderly individuals who suffer from various conditions and diseases, including cognitive impairment, for which they seek assessments, treatments or rehabilitation from care professionals (physicians, nurses, neuro-psychologists, psychomotricians, physiotherapists, nutritionists…). Although the whole experimentation is low-risk and considered non-interventional, as no invasive techniques *(e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)* and no medical interventions are planned, specific measures are required to guarantee the rights of participants, preserve their dignity and to ensure their safety, taking into account their potential vulnerabilities.

The following sections provide the necessary details about SPRING's ethical strategy for the main experiments, conducted at Broca's DCH : Section 3.3.1. describes the issues related to the vulnerability, the dignity and the safety of the participants. Section 3.3.2. provides information about the creation process of this ethical strategy. Despite the ongoing pandemic, professionals were involved in the early phase and provided guidelines about the overall conduct of the experimentation within the hospital facility. Section 3.3.3. will provide details about the procedures of recruitment and the strategy to mitigate the harmful effect of the experiments on the participants.

Note : This strategy will be described in the application submitted to the relevant French ethics committee (*Comité de Protection des Personnes*) for approval. Due to the Covid-19 outbreak in France, the team was forced to suspend the application process. It will resume as soon as the situation in the inner city of Paris allows it. In particular, further consultations with healthcare professionals are necessary to validate recruitment and implementation procedures, but this is currently impossible as all of the DCH professionals have been requisitioned to care for covid patients. Until they are again available, the content of the following sections is provisional, and may change significantly if requires.

3.3.1 Vulnerability of potential participants

The participants are considered vulnerable for various reasons and to varying degrees:

Part of the participants are **patients** from Broca's DCH. Due to the DCH's specialization, a significant portion of them may have neurocognitive disorders, which cause them to consult. They may also suffer from various conditions and/or live with disabilities, age-related or not, which induce several functional impairments (hearing, sight, motricity…). Many participants may also have difficulties with language or struggle to understand the purpose and the content of the project.

Patients with significant cognitive impairments may also live under legal guardianship, which requires a specific consent process. For people with mild or no cognitive disorders, participation may also be challenging. Some may be reluctant to participate because of low digital literacy. Conversely, some may feel that their refusal to participate in the study may affect the quality of the care they receive. In this case, the interaction with the robot may be

[3] https://medical-dictionary.thefreedictionary.com/day+hospital

understood as a major alteration in the care process and may generate additional stress for the participants.

Informal caregivers, or whoever accompanies the patients on the day of the experiments, may also suffer from various conditions/disabilities, given that many are as old as the person that they accompany (spouse, sibling…). Moreover, the burden of tending to their loved one's daily care and needs may already be hard to bear. For them, participation may be experienced as an additional and unnecessary load, while they may fear that refusing to participate may affect the quality of the care their loved one receives.

Professionals from the DCH can also be considered vulnerable, although their vulnerability derives from other factors. In this case, the hierarchical relation with the chief investigator may make them feel forced to consent to the experiment even if they are reluctant. The presence of the robot in the waiting room may also be seen as a potential additional load and constraint in their daily care practices.

The consortium will put organizational and technical measures in place to mitigate the potential adverse effects of the experiments on vulnerable participants. These measures are extensively described on sections 3.3.7.

3.3.2 **Dignity concerns**

Without appropriate measures, the main experiments may also threaten the dignity of the participants, especially elderly patients from the DCH. Although not intentionally, some events may emphasize their vulnerable condition, their disabilities or make them feel publicly stigmatized.

Persons with cognitive impairments could face difficulties when interacting with the robot. They may struggle to understand its speech or to figure out what the purpose of the interaction is. The situation may generate confusion that emphasizes their actual condition.

Other participants may share personal information with the robot, assuming that the conversation is private. Due to technical limitations, the robot may not be able to fully discriminate sensitive from non-sensitive information. The robot may then disclose this information to the public of the waiting room, whereas it should have been kept private (e.g.: A patient gives details about her/his day's schedule and the robot repeat it loudly to ensure it understood well).

In a worst case scenario, the mere presence of the robot may be a source of discomfort. Patients may experience the robot's presence as emphasizing their condition or their status in the DCH. Although it is unlikely, this may generate a feeling of infantilization or stigmatization in the most vulnerable persons who attend the hospital waiting room.

The consortium will also put organizational and technical measures in place to protect participants. These measures are described in section 3.3.7

3.3.3 **Safety**

All operations will take place according to safety procedures defined by PAL Robotics. The industrial partner PAL, based in Spain, is drafting a complete description of the security measures and security assessment. Considerations in this document are based on the ISO norms UNE-EN-ISO 13482, Appendix A regarding "Robots and robotic devices, Safety

requirements for non-industrial robots and non-medical personal assistance robots". The security measures are drafted by following the guidelines for submission to receive the CE certification (Directive 2006/42/EC) after the end of the project. As this document contains confidential information it is not yet possible to communicate it publicly.

This procedures guarantees an already significant level of safety for participants. However, the use of an imposing humanoid robot in a potentially crowded environment, with many frail persons with motor or sensory disabilities, raises specific questions of safety beyond the usual concerns one has to deal with when deploying a robot in a public place.

Therefore, during the experimentations, the investigators will follow additional safety procedures to protect even the most frail users of the DCH (see section 3.3.7).

3.3.4 Consultation and co-creation with professionals

Since the kick-off of SPRING, held in Paris on the 12th and 13th February 2020, AP-HP's research unit (called Broca Living Lab, BLL) has worked in close collaboration with Broca Hospital staff. Following the BLL's bottom-up approach, the ethical and the operational strategies were defined with the help of professionals working in the DCH, to ensure the adherence of the professionals with the project and maximize its overall chance of success. From late February to early March 2020, several meetings and interviews were scheduled, and questionnaires were also issued to collect insights from the workers of the service, the relevance and the feasibility of the use cases submit in the project's proposal.

Unfortunately, due to the Covid 19 outbreak, the DCH was shut down in March until further notice and most of its staff were reassigned to other units. All the upcoming meetings with DCH professionals had to be postponed and are yet to be rescheduled. Therefore, although the following procedures were defined using the information gathered from DCH professionals before mid-march 2020 when the DCH was operating, they may undergo significant reworking once the consultation process resumes.

As of mid-march 2020, the BLL had consulted with:

- The head of security of Broca hospital,
- Geriatricians from Broca Hospital (including, but not limited to, geriatricians of the DCH)
- Various professionals from the DCH, including the head physician, nurses, psychologists and receptionists

The consultation process is described below.

In early February, the BLL scheduled a meeting with the head of security of the Hospital. The main objective of the meeting was to discuss the legal implications of the experiment, and the necessary procedures to follow to comply with the current legislation. It was determined that although standard procedures did exist to authorize the installation of cameras in the hospital, they were not adapted to the needs of the project, as the recordings were supposed to be destroyed after a short period, while we needed to keep the data for longer to train and evaluate the algorithms developed by the consortium.

The following month, BBL's members introduced the basics of the project in several meetings with the care professionals of the hospital. SPRING's main objectives and the foreseen use cases were presented during one of the weekly staff meeting, which gathers most of the physicians working in the hospital. Although half of the meeting had to be dedicated to the

upcoming pandemic, BLL eventually received endorsement from the staff members. Another meeting was scheduled with the professionals from the DCH. BLL researchers introduced SPRING's main objectives, its use cases, and discussed the overall strengths/weaknesses, opportunities/threats of the project. Short, anonymous questionnaires, designed with HWU, were also distributed to those who attended the meeting (Annex 4).

Meanwhile, BLL conducted several interviews with DCH professionals. An extensive interview with the head of the DCH helped to understand the specificity of the patients, and to define the ethical strategy accordingly. Other interviews with psychologists, nurses and caregivers from the service provided valuable information about the daily work routine of the professionals and the organizational issues that SPRING partners should be aware of. These interviews helped the BLL team to design procedures for recruitment and experimentation that would hopefully provide good scientific results yet keep the impact on routine care to a minimum.

However, the Covid 19 outbreak in France interrupted the consultation process before this design could be presented, discussed and iterated on with the staff. Thus, the version that is presented here is subject to change when consultations can resume. Planned actions are : a second meeting with the Head of the DCH, focused on refining the strategy to deploy the robot in the waiting room without threatening people's privacy; focus group meetings with hospital staff (including, but not limited to the DCH) to discuss the main findings of the questionnaires and the ethical implications of the project; extensive semi-structured interviews and focus group meetings with DCH professionals to anticipate the organizational impacts of the project, further refine processes to limit disturbances to routine care and ultimately validate the entire protocol collectively.

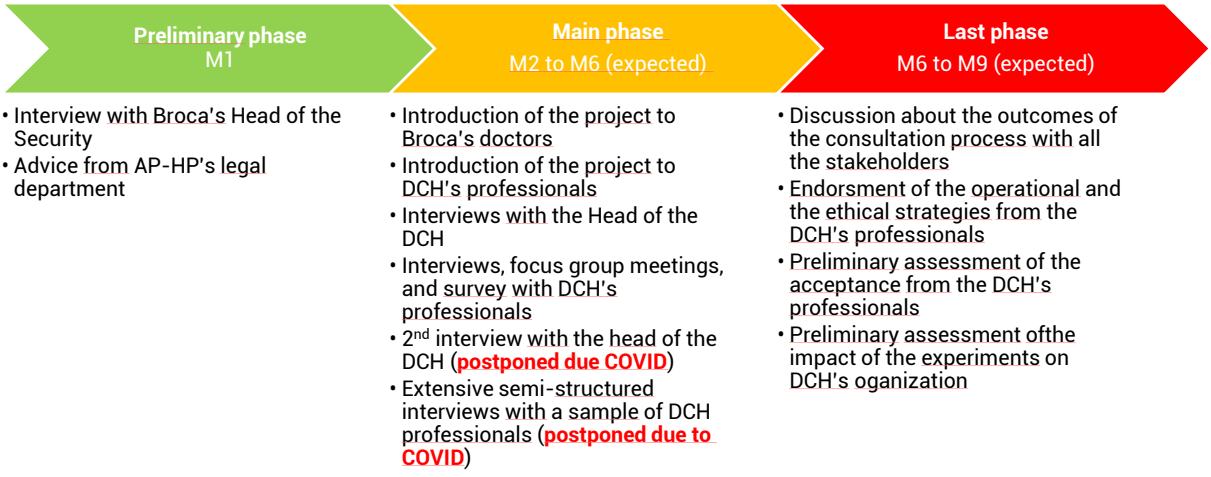

Figure 1 : The 3 steps of the consultation process with Broca's professionals, which should have ended in M6 but had to be postponed due to the Covid epidemic

3.3.5 **Recruitment procedures with inclusion and exclusion criteria**

As stated before, the goal of this bottom up methodology is to ensure that the research protocol does not introduce any significant distortion of normal care and preserves the privacy and dignity of all patients, caregivers and professionals.

Inclusion and exclusion criteria

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Participants are recruited among a wide spectrum of persons: some are patients of the day-care hospital, others are informal caregivers who accompany them, as well as healthcare professionals who work at Broca Hospital. As such, the inclusion criteria is very simple : any user of the day-care hospital (e.g. patient, caregiver or professional) may participate if he/she gives written informed consent. Nevertheless, due to the specificity of the DCH, where a significant portion of the patients have cognitive disorders, exclusion criteria had to be defined to make sure that the data collected remained consistent, and to avoid any detrimental effects on the participants. Persons with severe cognitive impairment, defined as people with a Mini Mental State Examination (MMSE, test in local language: French) score lower than 10, are excluded from full participation as investigators would not be able to conduct comparable semi-structured interviews with them. They and, if applicable, their guardian may, however, consent to the robot's presence and thus are not automatically seated in the "robot-free" area. If a person with severe cognitive impairment wishes to interact with the robot, he/she may do so, but investigators will neither record interactions nor interview the person afterwards.

As users of the day-care hospital, patients under legal guardianship may participate if their legal representative consents. Their guardian, who necessarily participates in the organization of care and is thus in contact with the hospital, is informed through phone calls, mail or e-mail. If he or she agrees, the investigator sends a note of information and informed consent forms. If the representative does not consent to participate or fails to sign or return the consent forms, the patient will not be included.

For eligible but still potentially vulnerable participants, well in advance of the days when the robot's presence is expected in the DCH (frequency is one to two days per month), the investigator contacts all the users that will be present on that day. If the users express their interest in participating, the investigator sends or hands them a note of information and informed consent forms. The forms are adapted to suit the person's group (patients, caregivers or professionals) and describe the two possible levels of participation (see below).

The note of information introduces the objectives of the project and the experimentation. It also states the rights of the participant regarding his/her participation, in particular the right to decline to participate or to withdraw from the experiment at any time without any justification or consequence, as well as the processing, the use, the transfer and the dissemination of any personal data collected by the consortium during the experimentation, ensuring strict compliance of data management procedures with GDPR. The informed consent form covers the whole experimentation, including consent to participate as well as the authorization to collect, store, process and disseminate the data collected by the consortium, as long as it abides with GDPR.

The participants who express their desire to participate must return their forms duly signed before the experimentation, either by sending the form back to the investigator in advance or bringing it with them on the day of experimentation. Users who do not return a duly signed consent form, whatever the reason, are considered as declining to participate. Moreover, using the hospital schedule and the consent forms, the investigators keeps a record of who came in contact with the robot and when, so that relevant data can be erased afterwards if participants decide to withdraw.

More specifically, the procedure distinguishes between three cases, depending on the wishes of the potential participants:

- some may wish to participate fully in the research (e.g. they are willing to interact with the robot while in the waiting room and let the investigator access their medical data and interview them)
- some may consent to the robot's presence in the waiting room, and thus consent to be recorded "unintentionally", but not wish to participate in the research (e.g. neither the robot nor the investigator should interact with them)
- some may decline to be in the presence of the robot entirely, thus consent neither to interact with it nor to be recorded "unintentionally".

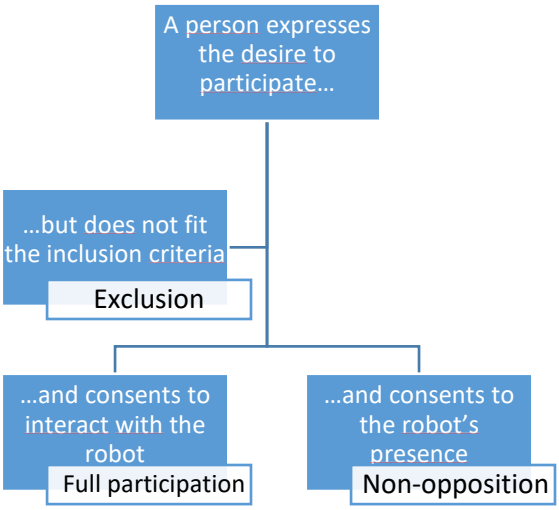

Figure 2 : The Inclusion Scenario

Patients and caregivers

Patients (or their guardian when applicable) who have an appointment scheduled on a day where the robot is supposed to be present in the waiting room of the day-care hospital are informed months in advance, by mail and/or e-mail, that the experimentation will take place. As part of the information process, a phone call is scheduled, during which a member of AP-HP's team, previously trained by the PEG for this purpose, or the PEG himself, introduces the research to the patients and ensures that they understand its objectives and as well as their rights regarding their participation and their personal data. If a caregiver is expected to accompany the patient, the patient (or his/her guardian when applicable) may also give the investigator his/her contact information so that he or she can also introduce the research to him/her. If any further questions arise from the patients or their caregivers, the investigator does his/her best to provide satisfactory answers.

Full participation of patients/caregivers - If the person and, when applicable, their accompanying caregiver express their desire to participate (e.g. they wish to interact with the robot), the investigator sends them the full information note (written in plain, easy to understand French, as validated by the ethics committee). This document provides all the necessary details about SPRING and the experimentation itself. The note states the rights of the participant regarding the collection, storage, transfer, process, and dissemination of the personal data, including medical data and interview recordings, collected during the experimentation, as well as the exploitation of the results of the study by the consortium members. The investigator also sends the corresponding informed consent forms. The patients and caregivers who express their desire to participate then return their forms duly

signed before the experimentation, either by sending the form back to the investigator in advance or bringing it when they comes to the hospital.

No participation of patients/caregivers, but no objection to the robot's presence – If the person and, when applicable, their accompanying caregiver do not wish to interact with the robot, but still consent to be in the waiting room while the robot operates, the investigator sends a simplified information note and an informed consent form which covers the collection, storage, transfer, process, and dissemination of the personal data collected during the experimentation, as well as the exploitation of the results of the study by the consortium members. In this second case, the forms clearly state that the person's medical file is not accessed by the research team, nor are any interviews performed. The patients and their caregivers who consent to the robot's presence return their forms duly signed before the experimentation, either by sending the form back to the investigator in advance or bringing it with him/her when he/she comes to the hospital.

Refusal from patients/caregivers - Finally, if the person or, when applicable, their accompanying caregiver does not consent to the robot's presence, fail to return their forms duly signed or retract their consent, they are not included in the study and keep their appointment scheduled regardless. Organizational measures are implemented on the day of the experimentation to ensure their full privacy: under the supervision of the professionals from the day-care hospital, the investigator sets up a "robot-free" waiting room where the robot is not allowed, so that patients and caregivers who decline to participate cannot be heard or seen by its sensors.

Healthcare professionals:

Professionals from the DCH must also give informed consent for the experimentation to take place. They are expected to be on duty with a busy schedule during the experiment, so most of them should only walk across the waiting room while the robot operates and never interact with it. Nevertheless, some may wish to participate fully in the study, so this case is also planned for. The needs of professionals differ from the rest of the participants: they are easier to reach and are considered less vulnerable. Thus, instead of systematic one-to-one recruitment interviews, group information sessions will be organized during staff meetings to discuss the experimentation, during which investigators will answer workers' questions about the robot and the protocol. Nevertheless, professionals will be given the opportunity to schedule one-to-one appointment with the PEG to discuss the experiment afterwards.

Full participation of DCH professionals - Workers interested in participating will be given a full information note, providing all the necessary details about SPRING and the experimentation itself, including their rights as participants and regarding the collection, storage, transfer, process, and dissemination of the personal data collected during the experimentation, as well as the exploitation of the results of the study by the consortium's members. Should they consent to interact with the robot and be interviewed by the researchers, they will sign a corresponding consent form, covering the entire duration of the study, as they will most likely be present on more than one day where the robot is deployed. Using the team schedule and the consent forms, the investigators will keep a record of who came in contact with the robot and when, so that relevant data can be erased afterwards if participants withdraw their consent.

No participation of DCH's professional, but no objection to the robot's presence – For those who do not intend to interact with the robot, but consent to be in the waiting room while the

robot operates, the investigator will issue notes of information stating their rights regarding the collection, storage, transfer, process, and dissemination of the personal data collected during the experimentation, as well as the exploitation of the results of the study by the consortium members. Should they consent to the robot's presence, they will sign a corresponding consent form, covering the entire duration of the study, as they will most likely be present on more than one day where the robot is deployed. Using the team schedule and the consent forms, the investigators will keep a record of who came in contact with the robot and when, so that relevant data can be erased afterwards if participants withdraw their consent.

Full refusal from professionals – Professionals who do not consent to the robot's presence on the days they are working will be able to reschedule their shift without any adverse consequences on their professional activity. Workers' schedule is known well in advance, and the team is used to participating in research protocols and reorganizing to do so when necessary, so this should not cause significant problems in the organization of care. Schedules will be checked regularly to ensure that on the days where the experimentation takes place, only consenting members of the staff are present in the waiting room.

APHP, as the ethic guarantor of the project, keeps a digitalized copy of all the forms and stores them in a secured encrypted server according to the reference methods it uses for clinical trials. Once digitalized, the hard copies are systematically destroyed. Copies of the notes of information and the different types of informed consent forms are appended to the deliverable (see ANNEX 4)

The Table below summarizes the different cases where the participant is fully included, included under specific conditions or not included excluded

	Fully Included	Included under specific conditions	Not included
Person who expresses the desire to participate, who is not suffering from severe cognitive impairments	X		
Person who refuses to participate but does not oppose to the robot's presence		X	
Person with severe cognitive impairment (≤ 10 MMSE) accompanied by her/his guardian		X	
Person with severe cognitive impairment (≤ 10 MMSE)			X
Person who does not express the desire to participate			X
Person who fails to return the informed consent duly signed			X

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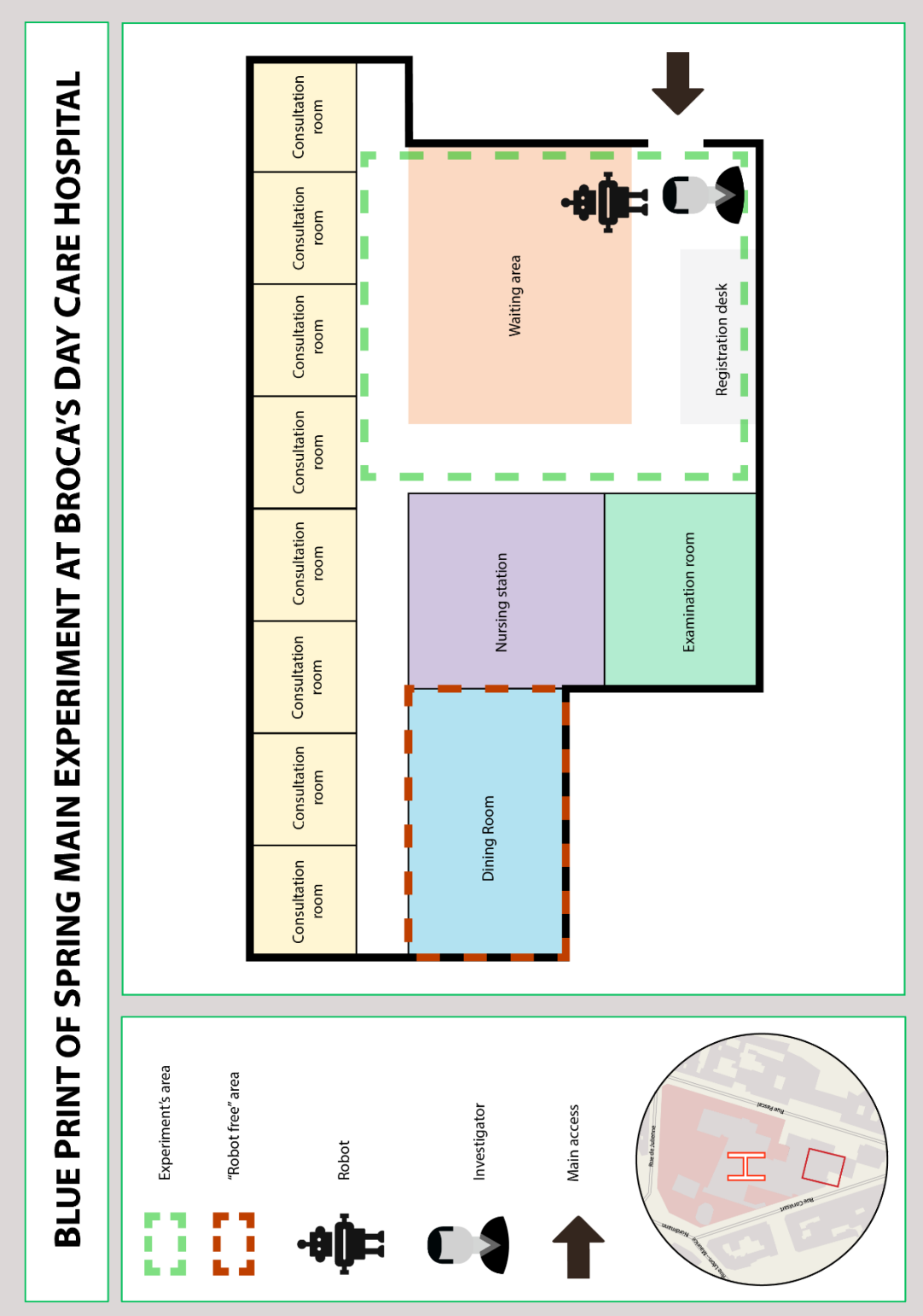
3.3.6 **Welcoming procedure on days of experimentation**

To minimize disturbance to normal care practices, the investigators will welcome all the patients and caregivers who have an appointment scheduled at the DCH as they reach the main access of the hospital, in the main hall. For participants who consented to interact with the robot or did not object to being in the waiting room while the robot operates, the investigator ensures once again that the basics of the experimentation are well understood and reminds them that they may withdraw their consent at any time without any justification or adverse consequences. They then enter the day-care hospital's facility and will be seated in the area where the robot operates.

Conversely, those who already refused to participate prior to the day of the experimentation or wish to withdraw will be seated in the area where the robot is not allowed to operate.

Finally, if a participant decides to withdraw from the study while the experimentation is taking place, the investigators will switch the robot off, accompany the person to the "robot-free" area and resume the experimentation with the remaining participants (see plan next page).



This document is designed by Broca Living Lab (APHP). The robot and the investigator are free-license pictograms borrowed from Vecteezy.com

3.3.7 Guidelines to Ensure Participants' Safety and Dignity

Co-creation of the experimental process through multiple information sessions and workgroups organized by the investigator with the medical staff should ensure that the

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disturbance of care practices and the potential harm caused by the research is as low as possible for those who do consent to participate. Nevertheless, as participants may be vulnerable and thus still feel pressured to participate, the following procedures are set up to prevent forced participation:

- All the experimental sessions will be supervised by a clinical psychologist. If, at any given time, if the person seems reluctant, confused, disturbed, disoriented or expresses any difficulty to proceed, the psychologist may choose to interrupt the experiment and discard the data collected with the corresponding participant. This applies for all the participants.
- On the day of experimentation, patients under guardianship will be shown the robot and given again the opportunity to decline to participate even if their guardian has given consent.
- Regular progress meeting will be conducted with DCH professionals to update them on the study. They will be reminded on these occasions that they can withdraw from the study at any time without any justification or adverse consequences on their professional activity.

Regarding the potential threats to the dignity and psychological well-being of the participants, the investigator decided to:

- Prevent any disclosure of sensitive information by instructing participants not to share any personal information with the robot. While introducing the experimentation to the participants, the investigator will stress this issue. If, however, sensitive information is shared with the robot, investigators will erase the relevant part of the data once the interaction is over.
- Prevent any user's excessive fatigue, by instructing the supervising psychologist to terminate the current interaction if it seems to trouble the participant.
- Avoid any additional stress from the patient by reminding the participants that the experimentation will not modify their schedule and that they are free to disengage whenever they feel like. Meanwhile, the investigator will tell care professionals that they are free to interact with the participants, regardless of the course of the experimentation.

Regarding the potential threats to the safety of the participants, the investigators will always be present next to the robot to:

- Warn each participant that she or he cannot lean on the robot or make any move that may destabilize it.
- Ensure that a safe distance is always kept between the participant and the robot during the interaction (said safe distance may depend on the type of interaction and user).
- Watch out for anything that may harm the participants and pause the experimentation whenever necessary.

Regarding the handling of adverse events, if some do occur in spite of the precautions described above:

- If an unexpected and potentially harmful event occurs, the investigator will press the emergency button on the back of the robot to switch the robot off, and ensure that no harm incurs to the participants, or anybody around. In case any potential harm is suspected, the investigator immediately calls for the help of a care

professional from the day-care hospital to assess the severity of the situation and follow his/her directions. The participant is excluded from the study and his/her data is discarded.

- When such an event occurs, if it raises any doubt about potential future harm, the experimentation is halted and may only resume once the incident has been analyzed by the team, and safety procedures have been updated accordingly.
- If harm does occur, the situation is handled in accordance with good experimental and clinical practice guidelines and national and international laws and regulations. Steps are taken as required, for instance informing the local responsible ethical authorities or in severe cases cessation of the study (this is very unlikely for our kind of experiments). Emergency services are notified if needed. All adverse events are followed until they have abated, or until a stable situation has been reached. Depending on the event, follow-up may require additional tests or contact with psychologists or medical specialists.

3.3.8 **Handling of incidental findings:**

No medical exams or evaluations will be conducted for this study. The only medical data reviewed will come from existing patients' files, which will already have been analyzed by the regular care team. Therefore, incidental findings are very unlikely. Should they still happen, for example if the researchers, when reviewing the files, notice a reporting error that may have medical implications, or if a patient reveals previously undisclosed critical medical information, the principal investigator, Pr. Rigaud, who heads both the research and care teams, will be notified and decide on further action if necessary.

3.3.9 **Contingency plan**

While the experimenters attempt to design feasible and acceptable recruitment and experimentation plans, the consortium understands that project remains ambitious. As stated in the original project proposal, two main risks have been identified that may prevent the experimentation from happening as described above:

- The ethic committee may disapprove of the proposed plan and prevent the experimentation from taking place in the DCH
- Even with ethical approval, day-care hospital workers may judge that, upon implementation, the protocol disturbs care practices in an unmanageable way.

To take these risks into account, the consortium has set up a contingency plan. In this case, the investigator would simulate the day-care hospital's environment within the Broca Living lab's controlled environment, as well as set up experiments in the day-care hospital outside of business hours. Participants would then be volunteers recruited among the Living Lab's users, who are elderly persons beyond 60, with their caregivers when relevant, and voluntary healthcare professionals, outside of their working hours. This procedure would be less realistic, thus not as satisfactory from a scientific point of view, but it would raise significantly less organizational and ethical issues, as it would not involve the processing of any medical data and would obviously not disturb care practices.

As volunteers would be recruited without any medical criteria, the validation of the local ethical committee of Paris University would suffice, instead of approval from the *Comité de protection des personnes*. Still, the investigator would ensure that the procedure complies

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with relevant ethical and legal frameworks, including GDPR : as in the standard scenario, the investigator would introduce the research to the volunteers by phone or during a meeting, and ensure they understood its objectives as well as their rights regarding the personal data protection policy of the consortium. The investigator would also state that she/he is open for any other questions. Should the persons express their interest in participating, the investigator would provide them with an information note, stating all the necessary details about SPRING and the experimentation itself, including the rights of the participant regarding the collection, the storage, the transfer, the process, and the dissemination of the personal data collected during the experimentation, as well as the exploitation of the results of the study by the consortium's members. Then, participants would sign the relevant consent form, which would be the same for everyone, unlike in the standard protocol.

On the day of the experimentation, as the volunteers reach the Broca Living lab, the investigator would welcome them and ensure that the basics of the experimentation are well understood, answer any further questions, and remind participants that they may still withdraw their consent without any justification or consequences, before starting the experimentation if no objections are raised.

As in the standard protocol, using the experiment schedule and the consent forms, the investigators will keep a record of whom participated when, so that relevant data can be erased afterwards if participants so require.

During the experiment, a scripted scenario would be introduced to the participants, based on the foreseen use cases. Volunteers will be told to act as patients, caregivers or care professionals, depending on their actual profiles, and would all interact with the robot during the experiment.

4 DATA PRIVACY AND MISUSE OF RESULTS

4.1 Legal context

SPRING is an international research project, which involves partners from all over Europe and Israel. It relies on the collection, storage, transfer and processing of personal data, collected in France through experimental trials. The sensitive nature of the project raises many legal issues. Ever since the kick-off of SPRING, INRIA and AP-HP research teams have worked in close collaboration with their legal department to determine the applicable legal framework and ensure the strict compliance of the project with the legislation. This section describes the principles that the consortium intends to follow as well as the legal framework that applies to SPRING. It provides the legal position of the consortium, especially towards GDPR, which stands as the main binding regulation in the project.

This section gives information about the international and European frameworks in the field of data protection while section 4.2 details the applicable articles and recitals from GDPR and, when necessary, the measures implemented by the consortium to comply with them.

International and European Instrument in the Field of Data Protection

Today the processing of personal data is a key activity for many entities, both private and public, and personal data flows on a global scale. Despite previous attempts, there is no unified legal framework or binding standards regarding the protection of personal data and the safeguarding of people's privacy, on a global scale (Kuner 2009). But most of today's international and regional legal documents are indebted to the international treaties of the post WWII era, which have defined core principles for the protection of people's right, including the right to privacy. Although data is not explicitly mentioned, Article 12 of the Universal Declaration of Human Rights (UDHR)[4] and Article 17 of the International Covenant on Civil and Political Rights (ICCPR)[5] state that « *No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honor and reputation. Everyone has the right to the protection of the law against such interference or attacks*. ».

In the last decades of the 20th century, these principles have become outdated. With the rise of computing technologies, computers have been increasingly used to process and transfer personal data. The new processing capacity changed the meaning of "privacy", which was merely a philosophical concept inherited from Enlightenment (Kirby 2011). Concerns have emerged about the extent to which inconsistencies among laws might disrupt the increasingly global flow of information (Cate, Cullen et Mayer-Schonberger 2013). This technological shift urged multilateral entities to come up with new frameworks.

In 1980, the Organisation for Economic Co-operation and Development (OECD) published the Guidelines on the Protection of Privacy and Transborder Flows of Personal Data which has been recognized as the first internationally agreed upon set of privacy principles (OECD 2013)

[4] https://www.un.org/en/universal-declaration-human-rights/ Consulted on the 28th of April

[5] https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx Consulted on the 28th of April

and have become the common base for most national laws governing data protection (Cate, Cullen et Mayer-Schonberger 2013).

In 2013, the OECD Council updated its guidelines significantly to address new challenges : "The volume of personal data being collected, used and stored; The range of analytics involving personal data, providing insights into individual and group trends, movements, interests, and activities; The value of the societal and economic benefits enabled by new technologies and responsible uses of personal data; The extent of threats to privacy; The number and variety of actors capable of either putting privacy at risk or protecting privacy; The frequency and complexity of interactions involving personal data that individuals are expected to understand and negotiate; The global availability of personal data, supported by communications networks and platforms that permit continuous, multipoint data flows."(OECD 2013, p3-4)

In Europe, the Charter of Fundamental Rights of the European Union (CFR) was created and ratified in 2000. The document outlines the fundamental rights enjoyed by all EU citizens regarding civic, political, economic and social rights. Unlike the UDHR, the CFR explicitly addresses the issue of personal data protection. Article 8 states that "*1. Everyone has the right to the protection of personal data concerning him or her. 2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified. 3. Compliance with these rules shall be subject to control by an independent authority*[6]*."* Since the application of the Lisbon Treaty, in 2009, the Charter has the same enforceable value as the European Union Treaties.

Finally, in 2018, the General Data Protection Regulation was implemented in the European Union with intention to "*lay down rules relating to the protection of natural persons with regard to the processing* of personal data and rules relating to the free movement of personal data", «protect fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data", and facilitate the "free movement of personal data within the Union" (GDPR, Chapter 1, Art. 1). GDPR replaced the former Directive 95/46/EC, enforced in 1995, which was greatly influenced by OECD's guidelines of 1980. Today, GDPR is the binding framework for every EU's members for matters of personal data protection.

SPRING adheres to the principles defined in:

- Article 12 of the Universal Declaration of Human Rights (UDHR) / Article 17 of the International Covenant on Civil and Political Rights (ICCPR)
- Article 8 of the Charter of Fundamental Rights of the European Union (CFR)
- Chapter 2 of the General Data Protection Regulation

4.2 SPRING Data privacy and security policy

According to the main strategic objectives of the project, the consortium intends to enable the robot's perception in complex, unstructured and populated environments (StO-1.), and to

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT Consulted the 28th of April

enable the sensor-based (data-driven) and knowledge-based robot's actions for multi-modal multi-person interaction and communication (StO-2). To achieve these goals, the partners need to automatically process a significant amount of personal data, most importantly the video and audio recordings made by the robot, which can be considered of biometric nature. Following the Article 9 of the GDPR, the processing of biometric data is prohibited, except for the purpose of "public interest, scientific or historical research […] or statistical purposes », and only if the processing is « proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject ». (Article 9.2.(j)). The consortium is thus allowed to process personal data the robot will collect only under specific conditions.

The following section details the strategy of the consortium to implement the organizational and technical measures required by GDPR.

4.2.1 Organizational measures

As agreed in the consortium agreement, signed by all partners, the data controllers of SPRING are designated to be AP-HP and INRIA. They are responsible for defining the organizational and technical measures needed to protect and secure the personal information of the participants, in accordance with recital 78[7]. The other partners are considered as data processors and must follow the procedures dictated by AP-HP and INRIA. Three main persons are involved in this oversight : two Data Protection Officers (Article 37.1(c)), who have the « expert knowledge of data protection law and practices » (Article 37.5) to enforce GDPR and ensure the strict compliance of all consortium's members with this general frame of regulation as well as with each specific national legislation (Article 39.1(b)).

Philippe Tourenne, DPO for AP-HP, will oversee matters related to the collection and manipulation of data by AP-HP's team, including video and audio recordings but also medical information from patients' files. He will also oversee the transfer of the audio and video recordings to INRIA. AP-HP will not transmit any data directly to partners besides INRIA. Medical data will never be transferred outside of AP-HP and will remain accessible solely by authorized members of AP-HP's team.

Anne Combes, DPO for INRIA, will collaborate with Mr. Tourenne on the transfer of video and audio data from AP-HP to INRIA. She will then oversee the transfer of part of this data from INRIA to other partners. She will ensure that they only access the data that is strictly necessary for them to conduct their work throughout the project and that they perform their activities in accordance with GDPR and the consortium agreement, which specifies their role as processors. Each partner also has its own DPO, designated in section 3.2.2., who is in contact with Ms. Combe to this end. The DPO of each partner is responsible for providing Ms.

[7] « The protection of the rights and freedoms of natural persons with regard to the processing of personal data require that appropriate technical and organizational measures be taken to ensure that the requirements of this regulation are met. In order to be able to demonstrate compliance with this regulation, the controller should adopt internal policies and implement measures which meet in particular the principles of data protection by design and data protection by default. Such measures could consist, inter alia, of minimizing the processing of personal data, pseudonymising personal data as soon as possible, transparency with regards to the functions and processing of personal data, enabling the data subject to monitor the data processing, enabling the controller to create and improve security features. » (Recital 78)

Combe with proof of compliance from with each partner's own national legislation for issues related to the processing and the storage of personal data as well as with GDPR.

The DPO also guarantees that non-EU partners engage to comply with GDPR requirements. For HWU, which is based in Scotland, GDPR still applies until the 31st of December 2020. Although UK's future policy toward personal data protection is to yet be determined, APHP will ensure the strict compliance of HWU with GDPR if the post-Brexit UK's standards were to be less constraining than GDPR. The same principle applies to BIU, which is based in Israel.

The Executive Committee of SPRING also co-opted a member from APHP, Mr. Samuel Benveniste, as the project's ethics guarantor (PEG) to oversee procedures both in terms of research ethics and data protection. Although his primary role is to ensure that all the research done in SPRING respects the rights of all research participants and is properly validated by the relevant ethics committees, he also collaborates with the DPOs on the protection of personal data, as the two matters are closely linked.

Spring's ExCom appointed AP-HP as the ethic guarantor of the project. AP-HP will ensure the compliance of all partners with the consortium's ethical policy defined in the consortium agreement, signed by all partners. AP-HP compelled all partners to co-opt their own local Data Protection Officer and to provide proof of compliance with GDPR.

INRIA and AP-HP, as data controllers, will ensure that « the data processed is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed » (GDPR, Article 5.1 (c)) and that personal data are processed « only if the purpose of the processing could not reasonably be fulfilled by other means » (GDPR, Recital 39).

Finally, to ensure that personal data are not kept longer than necessary, all video and audio data will be destroyed two years after the end of the project. The controllers will also make sure that every reasonable step is taken to ensure that personal data which are inaccurate are rectified or deleted (GDPR, Recital 39), and allow participants to ask for their data to be deleted. The procedures to request erasure will be described in the information notes and consent forms that the participants sign.

4.2.2 **Data Minimization Principles**

SPRING experiments imply the collection of personal data from various individuals (volunteers, patients, caregivers, healthcare professionals). INRIA and AP-HP, as data controllers, will ensure that « the data processed is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed » (GDPR, Article 5.1 (c)) and that personal data are processed « only if the purpose of the processing could not reasonably be fulfilled by other means » (GDPR, Recital 39).

Unfortunately, in many cases, no fully satisfactory alternative is currently available to the partners to avoid collecting and using personal data:

- By the end of the project, the SPRING's robot is expected to operate in a cluttered and populated space (SpO-1.1). To develop such ability, the robot must process audiovisual data to identify its physical and social environment, to map the actual location of persons and objects in its surroundings and to navigate accordingly. Whereas a pre-mapping of the vicinity would be enough to operate the robot in an empty space, real time mapping is necessary here. The location of persons and

objects in the surroundings of the robot is expected to be quickly shifting, as persons come and go.

- SPRING's consortium also intends to endow the robot with skills and ability to undertake autonomous, accurate (SpO-1.2) and acceptable (SpO-1.4) social interactions based upon the social, semantic, behavioral, and geometric representation of the immediate environment (SpO-2.2.). To do so, the robot needs to process audiovisual data to perform audio localization, to track and adapt its behavior to the movements of the speech sources, to locate and track the person who speaks, and to understand the behavioral and emotional states of the participants (SpO-1.2).
- The robot also relies on data processing to read and understand the non-linguistic transmission of information from the participants to the robot, or between the participants themselves, or to determinate features such as head and eye gaze, facial expressions, body poses, speed of speech or other physiological features, to engage/disengage and participate in conversations (SpO-2.1). Based on these elements, the robot would eventually assess the level of acceptance from users and behave accordingly (SpO-1.4) and perform as the situated interactions require (SpO-2.2).

Previous studies conducted in similar healthcare settings used a set of predefined behaviors or chose to tele-operate the robot during the interaction (Rouaix et al. 2017). Rule-based, pre-defined behaviors can be useful in very simple cases but quickly fail for more complex interactions, as many previous studies conducted on robots in healthcare settings have shown. Tele-operation, on the other hand, works very well but requires a high amount of human resources that negate the benefits expected from a robot in terms of cost control and organizational improvement.

That is why the goal of SPRING is to make the robot perform autonomously, based on its own perception of the situation of interaction. This can only be done through machine learning, which implies that the consortium collect and process real-world, personal data to achieve relevant operational performance for the robot.

However, to minimize the amount of sensitive data collected and processed, the consortium put several procedures in place:

First, no medical is collected nor processed by the robot, nor transferred outside of AP-HP by any means. The only medical data used will be data collected during standard care, extracted from patients' existing files by authorized AP-HP researchers for the final evaluations, with their explicit consent, through procedures submitted to and validated by the national ethics committee. None of this data will be transferred to other partners.

Second, real-world audio and video collection in the waiting room of the day-care hospital during opening hours, with actual users, will be limited. It will only be performed in the last part of the study, for final evaluations, and will be limited in time to one or two days per month. As much work as possible will be conducted using simulated interactions, with healthy volunteers, through experimental procedures that will be submitted to relevant ethical committees by each partner.

Third, whenever possible, existing, public AI training databases (such as databases for linguistics, facial features, etc.) will be used and the collection of new data will be limited to cases where it is needed due to specificities of the task at hand. The use of these databases will be described by partners in their respective applications sent to the relevant ethics committees.

4.2.3 SPRING's policy towards profiling and tracking

The SPRING robot does not perform any profiling as defined by GDPR[8] : the robot will not process the data it collects in order to individualize or categorize a natural person, based on personal qualities and attributes ascribed by the robot to the person (e.g. : the robot will not use data collected through audio-visual sensors to label the participants according to the beliefs, the way of life or the ethnicity).

Personal data collected through means of fieldwork techniques (questionnaires and interviews) will be used by AP-HP researchers to manually establish participant profiles to analyse preferences and interests regarding the use of health care robots, but this does not involve any automated processing technique, as the profiling will be done using qualitative analysis techniques performed by humans.

Out of the three main objectives, two could be considered as involving the observation and the tracking of the participants (StO 1 & StO 2). The success of SPRING depends on the ability of the robot to operate and perform social interactions in a cluttered space with a satisfying level of autonomy by the end of the project. The consortium intends to significantly improve the robot's ability to model its physical and sound environment and to identify the speakers in its surroundings. To do so, the robot will process audiovisual data, using object, body and face localization technologies as well as mutli-microphone sound localization to perform object and person tracking and map its dynamic environment. The robot will also read facial features to understand the emotional states of the participants and trigger the appropriate behavior. All this could be considered as amounting to a form of tracking and surveillance, especially from the point of view of healthcare workers who would be involved in the study for extended periods of time.

However, we chose a study design that minimizes the adverse effects that the observation and the tracking of the participants may generate over a long period:

- First, the rather low frequency of medical appointments (usually twice a year), and the rather low frequency of experimentations (once or twice a month), limit the probability of a patient or caregiver encountering the robot multiple times. This reduces the intrusiveness of observation and tracking techniques on individuals.
- Furthermore, the observation and the tracking of the participants will only happen within the boundaries of the waiting room, as the robot will have a clearly defined operating space.
- Moreover, the length of each day of experimentation is short, since it cannot exceed the opening hours of day-care hospital.
- Finally, the robot's memory of the people it encountered will be wiped every night, thus I will not recognize people if it “sees” them again.

4.2.4 Anonymization and coding of personal data

Article 32 requires the “pseudonymisation and encryption of personal data », « the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services ». Accordingly, Partners who undertake data collection and processing will anonymise data whenever possible. Unless required by law, only the study investigators,

[8] GDPR understands profiling as « any form of automated processing of personal data evaluating the personal aspects relating to a natural person » (GDPR, Recital 71).

members of the investigator's staff, and members of the local ethics committee and/or the local investigation review board will have authority to review such information, as well as the study records.

Throughout the project, investigators from AP-HP will collect personal data from patients, their caregivers and hospital professionals. They will use several fieldwork techniques such as observation, questionnaires and semi-structured interviews.

First, out of daily observations of the social interactions between persons who happen to be in the day-care hospital (patients, informal caregivers, hospital professionals), AP-HP investigators will produce a set of textual data that will allow HWU to train the conversational modules. This data will be transcribed manually, and AP-HP will ensure that no personal, medical or sensitive information, or any elements that could help to identify the speakers or anybody else, are transcribed, following ASA guidelines[9].

AP-HP investigators will also conduct semi-structured interviews with the hospital professionals and ask the patients and caregivers to fill out questionnaires after their interaction with the robot. Interviews and questionnaires will help AP-HP to assess the organizational impact of the robot and its level of acceptance from users. In the case of interviews with the hospital professionals, the investigators will transcribe the content of the conversations from audio recordings. As with textual information, they will not transcribe any information that may help to identify the speaker or any persons mentioned during the interview, following ASA guidelines. Once transcribed, the investigators will erase the recordings.

In both cases (questionnaires and interviews), the identity of the participants will be replaced with an id number. This unique participant identification number will be taken from a list of 5-number-long identifiers randomly generated beforehand by the PEG and communicated only to the researchers directly involved in the data collection. The identification between the id number and person will only be present in a secured data storage folder separate from the individual case report forms. Only the PEG will have access to this file. This will allow the PEG to process requests from participants to erase/modify, partially or totally the data collected during the experimentation.

Although the consortium's members will anonymize as much of the data they collect as possible, the audio and video data recorded by the robot cannot be anonymized (e.g. faces cannot be blurred or obscured), as one of the objectives of the project is for the robot to analyse facial features to perform behavior and emotion recognition to adapt its interactions. Thus, to evaluate the performance of the robot, this non-anonymized data will have to be annotated by hand. This fact will be clearly explained by the investigator to participants so that they give fully informed consent. Furthermore, the ethics guarantor of AP-HP and the DPO of INRIA will closely oversee the use of data (storage, transfer, processing and dissemination of the results), enforce thorough security procedures and make sure that the data is destroyed at most two years after the end of the project. The content of the recordings will always be stored separately from participants' names or identifiers.

[9] Association of Social Anthropologists of the UK and the Commonwealth (ASA). (2011) Ethical guidelines for good research practice. http://www.theasa.org/downloads/ASA%20ethics% 20guidelines%202011.pdf. Accessed July 10, 2013.

The data anonymisation/pseudonymisation techniques used by each partner regarding the pre-experiments performed on their own sites will be described in their applications to the relevant ethical committees.

4.2.5 Storage and transfer of personal data

As far as storage is concerned, during the experimentation, the robot will log on to a dedicated and encrypted wifi network. This network architecture ensures that the robot does not connect with any other of APHP's services. Furthermore, the investigator ensures that the robot's memory will be properly wiped out after each day of experimentation. Any sensitive data would not be kept within the robot's hard drives overnight.

Instead, at the end of each day of experimentation all data collected will be manually transferred and stored on a NAS server of capacity 4 × 8 TB, with a RAID 5 storage safety level. The server will be located in a closed room, within Broca's compound. Only two persons appointed by the governing body of SPRING will be granted physical access to this server: one from APHP, as Privacy and Ethics Guarantor, another one from ERM, as technical expert. The PEG will also perform first-level maintenance of the server if necessary.

To achieve overall and specific objectives, the consortium members need to transfer a significant amount of personal data between each other. As one of SPRING's controller, INRIA oversees the transfer of the data to the processors, according to what the tasks assigned to them require. In the meantime, APHP, who is the ethic guarantor of the project, ensures that all the partners comply with the privacy and ethics standards and European regulations.

The need for data of each processor is defined in the Work package and go as follows:

- UNITN: to develop technologies for analyzing human behaviors from multimodal sensors robotic platforms and semantic scene analysis (WP2, WP4 and WP5)
- CVUT: work on visual robot localization and online map update, as well as scene and situated interactions understanding (WP2, WP4 and WP5)
- HWU: works to enhanced Multi-User Conversations skills of the robot, especially visually grounded communication, adding dialogue to the interactive simulated environment and combining the high-level planner with the robot behavior system (WP5)
- BIU works enhanced auditory description and automatic speech recognition of the robot (WP3, WP4 and WP5)

	Auditory	Visual	Proprioceptive	Textual
INRIA (France)	YES	YES	YES	NO
UNITN (Italy)	YES	YES	YES	NO
CVUT (Czech Republic)	YES	YES	YES	NO
HWU (Scotland*)	YES	YES	NO	YES
BIU (Israel*)	YES	NO	NO	NO

*non EU member

Each partner is bound by the consortium agreement to use the data it is given access to only for the treatments defined by INRIA and APHP as data controllers. Non-EU members (UK and Israel) will follow the most restrictive legislation between GDPR and that of their country. If

any conflict arises because of national laws contradicting GDPR requirements, the partner will notify the executive committee, which will modify the work plan in consequence and halt data transfers if necessary.

As stated above, textual, auditory and visual recordings will be sent to HWU, which is based in Scotland, and BIU, which is based in Israel. The Ethic guarantor of the project enforce the strict compliance of all members with GDPR. As such, APHP ensures these two non-EU partners comply with GDPR's policy.

The transfer of data, either from the server to the partners and between partners, will have to go through a secured FTP connection that ERM will set up. All data sets will be encrypted during the transmission and local storage at partners' sites will have to be encrypted with the same level of security. The technical specifications for these hardware and transfer protocols will be determined precisely according to the results of the impact analysis ongoing at INRIA, under the supervision of Inria's DPO (Anne Combes) and the representative of the Defense Security Officer[10] (Serge Charles-Vallet).

4.3 Prevention of potential misuse of SPRING results

The scope of the project is defined by the consortium in the project proposal (Proposal number: 871245). SPRING aims to develop a socially assistive robot with the capacity of performing multi-person interactions and open-domain dialogue in healthcare setting. The 5 use-cases (welcome; check-in/check-out; consultation assistance; patient guidance; entertainment) defined for the main experiment are designed according to this particular institutional environment, and the technologies developed will mostly be suitable for reuse in similar settings, as ensured by data collection minimisation measures presented in section 4.2.2, limiting the possibilities for misuse. Furthermore, as specified in the consortium agreement, raw data will not be made public and only processed by the partners in the ways specified by the data controllers (AP-HP and INRIA). SPRING's research adheres to the principles defined by Horizon 2020 for matters related to privacy and fundamental rights (*Horizon 2020 in brief* 2014).

Nevertheless, risks of misuse do exist, both during and after the project:

- As detailed in section 4.2, the SPRING robot will process personal data collected from a significant number of vulnerable users. In this case, misuse would derive from the leak of personal data caused by the illegal and malicious intrusion of an unauthorized party in the project's server or during data transfer, or by a member of the consortium. This would disclose participants' personal information and may lead to harmful use of personal data.
- SPRING robot carries various sensors that allow it to track persons in space, to analyse their facial features or to understand the contents of their conversations. Whereas the use of this technology during the project is supervised, the robot's technology could conceivably be used for means of surveillance and control by authoritarian regimes (e.g. : to track people in public places; to extract personal information; to stigmatize or marginalize a person, or a group of people, based on their political opinion, their religious beliefs, their ethnicity or their sexual orientation)

[10] *Fonctionnaire Sécurité Défense* in French

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By design, organizational and technical safeguards are introduced by the consortium to avoid any misuse from the SPRING members, or by any external party, during the project:

- Spring's ExCom appointed AP-HP as the ethic guarantor of the project. AP-HP will ensure the compliance of all partners with the consortium's ethical policy defined in the consortium agreement, signed by all partners. AP-HP compelled all partners to co-opt their own local Data Protection Officer and to provide proof of compliance with GDPR.
- As explained above, the consortium implemented security measures to avoid any leak of personal data. During the experimentation, the robot will log on to the extranet via a dedicated and encrypted wifi connection. This network architecture ensures that the robot does not share a network with any other APHP service. Furthermore, the investigator ensures that the robot's memory will be properly wiped out after each day of experimentation. Any sensitive data would not be kept within the robot's hard drives. Instead, all data collected will be stored on a NAS server of capacity 4 × 8 TB, with a RAID 5 storage safety level. The server will be located in a closed room, within Broca's compound. Only two persons appointed by the governing body of SPRING will be granted physical access to this server: one from APHP, another one from ERM. APHP will also perform first-level maintenance of the server if necessary. The transfer of data, either from the server to the partners and between partners, will have to go through a secured FTP connection that ERM will set up. All data sets will be encrypted during the transmission and local storage at partners' sites will have to be encrypted with the same level of safety.
- Throughout the project, SPRING's partners are bound to the consortium agreement, which defines the scope of the study and the authorized use of the data collected during the project. The processors are not allowed to go beyond what the agreement prescribes. In the case where a breach of the consortium's policy from a partner is reported, the controller or/and the ethic guarantor would take the appropriate measures, as detailed in the consortium agreement.
- INRIA, as the project's controller is currently running a risk-assessment audit to identify the risks associated with the project and the measures to address them. This document will be attached to the next ethics deliverables (D10.1 and D10.2) which will also contain the feedback and, if positive, the validation of the ethics committee.

Furthermore, the consortium also seeks to avoid any misuse of its technology after the end of the project:

- The consortium agreement defines the scope of the exploitation of the project's results. A specific agreement will be issued for further use of the technology, especially for commercial purposes. SPRING's partners would have to provide proof of compliance with the current regulation, and show that they do not intend to misuse the results of SPRING
- Misuses of the project's results beyond the reach of the consortium would fall under the current national and European regulations (e.g. : Exports of dual use technology to non-European countries are controlled by Council Regulation (EC) No 428/2009 and Council Regulation (EU) No 388/2012)

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5 CONCLUSION AND FUTURE WORK

SPRING is an ambitious project at the edge of innovation. All at once, it aims to tackle the limitation of today's social robotics, intends to support care professionals in their daily work and tries to provide an efficient and enjoyable robot companion to hospital's users. Therefore, the targets of the project are not only technological, but also social and economic.

Despite its interesting objectives, SPRING raises legitimate ethics and legal concerns. The acceptable use of a socially assistive robot in an eldercare facility, where most of the patients are expected to suffer from cognitive disorders, is a first challenge to address. The lawful collection, storage, transfer or processing of personal data of the participants is another. The present document specifies the consortium's ethics policy regarding these issues.

Since the kick-off of SPRING, in early February 2020, AP-HP, as the project Ethic Guarantor and INRIA, as the project coordinator, worked along with all SPRING partners to define the most appropriate ethics strategy. This deliverable is the first main outcome of this collective work. All the major concerns were addressed under scrutiny of the European legislation and guidelines. The deliverable outlines the ethical strategies that all partners have or will design to ensure that the privacy of the participants and the protection of their personal data, as GDPR stipulates. Special emphasis is placed on the project's main experiments, which are expected to take place in Broca's DCH waiting room. As due to the specificity of Broca hospital, which targets elderly patients most of them experiencing some level of cognitive disability, and because of the type of data processing intended by the consortium, there was a need to provide a higher level of detail of methods, procedures, and risks identification and management.

The deliverable helped to specify the organizational and technical measures required to address:

- The need to obtain consent from potentially vulnerable participants
- The need to conduct the experiments without affecting the quality of the care process or disturbing the work of care professionals
- The need to mitigate the effects of the experiments equally on the persons who will participate in the project and those who will not
- The need to protect the participant's data and safeguard their privacy, in strict compliance with GDPR.

This deliverable is a first major step toward the success of the project. It provides all SPRING's partners with a set of guidelines they could consult to ensure they comply with the project's ethics policy.

However, this deliverable is not sufficient. It will be complemented with additional contributions of SPRING's members. AP-HP will undertake an in-depth review of the relevant legislation, directives and guidelines to provide a more comprehensive approach of the legal framework of the project. The outcome of the safety assessment analysis, currently conducted by PAL, will help to improve the strategy of the consortium toward safety. The result of the impact analysis, ongoing at INRIA, will also allow the consortium to specify its strategy regarding the robustness of its system. The analysis is expected to provide valuable specifications about hardware and transfer protocols. Once these documents are issued, this deliverable will be updated and the documents will be appended. The experimental process described in this deliverable will also be updated according to new insights gained from

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further consultations with DCH professionals. If necessary, additional ethical analyses will be performed and included, to deal with potentially new issues raised by said consultations. For instance, an analysis of the philosophical implications of the spread of robotics in work places, particularly in health care settings, may be useful to understand the moral questionings that the experiments could bring. Finally, AP-HP will discuss the outcome of this consultation process with all stakeholders and collective work-sessions will allow the consortium to draft operational guidelines.

Afterwards, APHP will submit the final research protocol to the relevant ethic committee (Comité de Protection des Personnes) for approval. Proof of the application and the eventual validation of the committee, as well as the approval from local ethics committees obtained by each partner for their pre-experiments, will also be submitted as future deliverables before the start of the main experimentation phase.

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7.1 Annex 1. Pre-experiment ethics assessment for SPRING partners

Annex 1.1. The National Institute for Research in Computer Science and Automation (INRIA, France) pre-experiment ethics assessment

INRIA pre-experiment's assessment and ethic's procedure	
Country	France
Person in charge of ethics on site	PI: Xavier Alameda-Pineda Local COERLE contacts: Marie Lorphelin et Cédric Lauradoux National contact: Sylvain Petitjean
Testing procedure	Two different experimental procedures will take place 1- training of the AI (robot) with online databases of audio-visual content 2- training in a concrete setup in presence of people in a neutral room at INRIA
Type of population involved	1- People involved in the building of the databases 2- The experiment involves human volunteers' participants not having a subordinate relationship with the PI or ethics local contacts. All the people recruited for the recordings will be healthy adults.
Identified ethical issues	1- Use of existing databases. A list of databases to be used have been checked for participating conditions. 2- Collection of personal data (video and sound). Physical interactions between robot and researchers / participants Psychological influence on participants (limited because no direct interaction with the robot)
National ethics controlling body (if relevant for some of your experiments)	None
Reference ethics commitee for your local experiment (if different from the national ethics)	COERLE (Inria's Operational Committee for the assesment of Legal and Ethical risks).
National data privacy controlling body	CNIL (Commission Nationale Informatique et Libertés)
Data protection officer	Anne Combe

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Ethical procedures to perform	1- Databases will be checked for reducing the chance of ethical issues and conflicts 2- Project will be submitted to COERLE for review and authorization COERLE's answer is expected 2 months after the submission. In particular, COERLE will verify that there is no risk of injury to researchers and participants in their interactions with the robot used for the experiment. Information on the experiment as well as consent form will be produced in accordance with the EU recommendations
Compliance with regulations for the protection of personal data (GDPR)	The GDPR compliance of all existing databases used for the experiments will be checked. For experiment involving human participants, the participants will sign a consent form providing them with sufficiently detailed information on the experiment so that they can make an informed, voluntary and rational decision to participate. The data collection will be declared to the Inria's DPO and the local chief information officer who will both verify that the data collection complies with the GDPR.

Annex 1.2. The Department of Information Engineering and Computer Science of Trento University (UNITN, Italy) pre-experiment ethics assessment

UNITN pre-experiment's assessment and ethic's procedure	
Country	Italy
Person in charge of ethics on site	PI: Elisa Ricci
Testing procedure	Two different experimental procedures will take place 1- training of the AI (robot) with online databases of visual data 2- training in a concrete setup in presence of people in a neutral room at UNITN
Type of population involved	1- People involved in the building of the databases 2- The experiment involves human volunteers' participants not having a subordinate relationship with the PI or ethics local contacts. All the people recruited for the recordings will be healthy adults.
Identified ethical issues	1- Use of existing databases. A list of databases to be used have been checked for participating conditions, use conditions, etc (see attached file) 2- Collection of personal data (video). Physical interactions between robot and researchers / participants Psychological influence on participants (limited because no direct interaction with the robot)
National ethics controlling body (if relevant for some of your experiments)	None
Reference ethics commitee for your local experiment (if different from the national ethics)	Human Research Ethics Committee of University of Trento: https://www.unitn.it/en/ateneo/1755/human-research-ethics-committee
National data privacy controlling body	Garante per la protezione dei dati personali
Data protection officer	Avv. Fiorenzo Tomaselli
Ethical procedures to perform	1- Databases will be checked for reducing the chance of ethical issues and conflicts 2 - Submission of research proposals to the Ethics committee (IRB) as required.

Compliance with regulations for the protection of personal data (GDPR)	The GDPR compliance of all existing databases used for the experiments will be checked. For experiment involving human participants, the participants will sign a consent form providing them with sufficiently detailed information on the experiment so that they can make an informed, voluntary and rational decision to participate. Thy will also sign a document describing GDPR data treatment regulations.

Annex 1.3. The Interaction Lab of Heriot-Watt University (HWU, Scotland) pre-experiment ethics assessment

HWU pre-experiment's assessment and ethic's procedure	
Country	Scotland
Person in charge of ethics on site	Oliver Lemon
Testing procedure	To train and test multi-user spoken conversation with robots as decribed in the proposal the prototype systems will be deployed in a series of data collection experiments with human subjects. Firstly, in the University laboratory involving students and researchers as users, and secondly in local elder care facilities with residents and professionals. In each case, participants will interact with the systems on the basis of the use-cases defined in the proposal. Publicly available data sets may also be used for training the conversational AI.
Type of population involved	University students and research staff. Elderly people and health care professionals in local (UK) privately owned residential care homes.
Identified ethical issues	Data collected will include audio and video from which participants are potentially identifiable. Third- party Automated Speech Recognition will be employed; therefore, the vendor selected must have GDPR-compliant processes. Residents in care homes are a vulnerable group; some may lack capacity and be under Power of Attorney guardianship. Special care must be taken with these users to ensure that either they are able to give informed consent to participate in the studies, or such consent is obtained from their legally representative proxy. Where external databases are used AI for training, it must be confirmed these can be freely used for the project.
National ethics controlling body (if relevant for some of your experiments)	None

Reference ethics commitee for your local experiment (if different from the national ethics)	School of Mathematical and Computing Sciences Ethics Committee, University of Heriot Watt
National data privacy controlling body	ICO (Information Commissioner's Office)
Data protection officer	Heriot Watt Heritage and Information Governance: hig@hw.ac.uk
Ethical procedures to perform	Submission of research proposals to the Ethics committee (School of MACS, Heriot Watt) as required.
Compliance with regulations for the protection of personal data (GDPR)	HW will assess the need for a Data Protection Impact Assessment as part of the University's Ethical Approval Process. In compliance with GDPR all data collection will be on the basis of informed consent; all participants will sign an informed consent form prior to taking in part in experiments. All data will be pseudonymized, stored on a firewall-protected University server and accessed only by staff on the project.

Annex 1.4. The Acoustic Signal Processing laboratory at the Faculty of Engineering In Bar-Ilan University (BIU, Israel) pre-experiment ethics assessment

BIU pre-experiment's assessment and ethic's procedure	
Country	Israel
Person in charge of ethics on site	PI: Sharon Gannot; Person in charge of ethics: Alon Nusbaum, BIU RA
Testing procedure	Two different experimental procedures will take place 1- training of the AI (robot) with online databases of audio-visual content (part of the databases used by INRIA) 2- training in a concrete setup in presence of people in a neutral room at BIU acoustic lab
Type of population involved	1- People involved in the building of the databases 2- The experiment involves human volunteers' participants not having a subordinate relationship with the PI or ethics local contacts. All the people recruited for the recordings will be healthy adults. In some cases, the students in the lab will be recorded uttering neutral content.
Identified ethical issues	1- Use of existing databases. A list of databases to be used have been checked for participating conditions. 2- Collection of personal data (mainly audio). Physical interactions between robot and researchers / participants Psychological influence on participants is not expected, as the sentences will be neutral and not-personal. No physical risk from the robot is expected.
National ethics controlling body (if relevant for some of your experiments)	None
Reference ethics commitee for your local experiment (if different from the national ethics)	Institutional Review Board, Human Trials commission, headed by Pr. Yadid Gal
National data privacy controlling body	Privacy Protection Authority
Data protection officer	Alon Nusbaum
Ethical procedures to perform	1- Databases will be checked for reducing the chance of ethical issues and conflicts

	2- Submission of research proposals to the Ethics committee (IRB) as required.
Compliance with regulations for the protection of personal data (GDPR)	The GDPR compliance of all existing databases used for the experiments will be checked. For experiment involving human participants, the participants will sign a consent form providing them with sufficiently detailed information on the experiment so that they can make an informed, voluntary and rational decision to participate.

7.2 Annex 2. Main experiment ethic assessment from Broca Living Lab, Assistance Publique - Hôpitaux de Paris (AP-HP, France)

AP-HP pre-experiment's assessment and ethic's procedure	
Country	France
Person in charge of ethics on site	Samuel Benveniste
Testing procedure	To test the usability and acceptability of ARI in gerontological Healthcare the robot will be deployed in a day care hospital during around 20 non consecutives days where patients and professionals will interact with it according to the 5 use-cases defined in the proposal.
Type of population involved	Elderly people with and without neurocognitive disorders and health care professionals of Broca's hospital.
Identified ethical issues	Data collected is of audio and video type. It will be stored during a long period and transferred to other partners. People with neurocognitive disorders are vulnerable and often under guardianship. They must give their informed consent to participate in the studies. There is potential misuse of the data.
National ethics controlling body (if relevant for some of your experiments)	CPP Comités de Protection des personnes
Reference ethics commitee for your local experiment (if different from the national ethics)	CER of Paris Descartes University
National data privacy controlling body	CNIL (Commission Nationale Informatique et Libertés)
Data protection officer	Philippe Tourenne
Ethical procedures to perform	Official request for advice from CNIL on the exact nature of the video and audio data collected: is it medical data or not? Official answer expected in May or June. Submission of a research proposal to the Ethics committee (CPP) in March. Answer expected in June.
Compliance with regulations for the protection of personal data (GDPR)	AP-HP and INRIA together conduct data protection analysis. AP-HP, INRIA and

	ERM are conducting technical procedures to protect the transfer of data collected in the Hospital. The lawful base (as defined by GDPR) for data collection in this case is consent: all participants will sign informed consent forms before interacting with the robot.

7.3 Annex 3. Questionnaire to assess the expectations of day hospital professionals regarding their intentions to use the robot and the use cases envisaged for the main experiment

Annex 3.1. French version of the questionnaire

PROJET SPRING
Questionnaire à destination des équipes de l'hôpital Broca

Le projet SPRING vise à développer un robot social, nommé **ARI**, pouvant assister les équipes de l'hôpital dans leur travail d'accompagnement des patients et de leurs proches. **L'utilisation exacte du robot reste à définir avec vous.** Il pourrait par exemple se consacrer aux demandes les plus courantes et les plus répétitives survenant en salle d'attente. **Sa présence permettrait aux équipes de dégager du temps pour se consacrer aux demandes plus complexes.**

Pour cela, nous avons besoin d'identifier de manière précise les demandes du public.

Pourriez-vous, s'il vous plait, nous donner quelques exemples de questions que vous posent habituellement les patients et leurs proches en salle d'attente. Les demandes les plus courantes et les plus répétitives nous intéressent tout particulièrement.

Figure 1. ***Voici le prototype du robot ARI avec lequel il vous sera proposé d'interagir en 2021****.*

ARI est encore en développement, mais pourrait :

- Parler de manière autonome avec plusieurs personnes
- Se déplacer de manière autonome

Date :

Vous êtes : Psychomotricien / Ergothérapeute / Réceptionniste / Infirmier / Médecin / Psychologue / Cadre / Orthophoniste / Kinésithérapeute / Autre (précisez) : ……

1. **Quelles sont les demandes les plus courantes des patients et de leurs proches ?**

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Pour remplir le questionnaire, indiquez pour chaque demande des patients ou de leurs proches une brève description des réponses que vous donnez habituellement. Voici un exemple qui pourra vous aider à répondre :

Question : Patient/accompagnateur – « O*ù dois-je aller ensuite* ?» .....
Votre réponse : ex 1 : « *Indiquer la pièce du doigt et donner quelques informations* »
Ou
Ex 2 : « *Choisissez un siège, le docteur va venir vous chercher* »

Merci d'indiquer le plus d'exemples possible.

Question :
.....

Votre réponse : ……..……..

Question :
.....

Votre réponse : ……..……..

2. Dans la salle d'attente, à quoi le robot ARI pourrait-il vous être utile ?

Comment pourrait-il vous servir ?

……
……
……

3. Les fonctionnalités présentées ci-dessous correspondent à des usages possibles du robot dans une salle d'attente. Vous serait-il possible d'évaluer la pertinence des propositions ci-dessous pour votre service (0 = « pas du tout utile » à 5 = « très utile »). Vous pouvez attribuer le même score à toutes les propositions.

Fonctionnalités	**Score (0 à 5)**
Accueillir les patients	

Aider à l'enregistrement à l'arrivée et au départ des patients	
Information sur les consultations ultérieures	
Guider et orienter les patients dans l'espace	
Proposer un divertissement aux patients et à leurs proches en attendant les rendez-vous.	

Annex 3.2. English version of the questionnaire "SPRING Project - Hospital Staff Questionnaire".

The EU SPRING Project aims to develop a conversational robot that can support hospital staff in assisting patients and their companions during visits to the Memory Clinic at APHP. The robot will focus on handling the most common, repetitive enquiries made in the waiting room, giving hospital staff more time to focus on more complex enquiries and other aspects of patient care.

With that in mind, please give as many examples as possible of the types of questions asked by patients and their companions in the waiting room. We are especially interested in common, repetitive enquiries initiated by the patient or their companion(s).

For your response -- please give a brief description of a typical response that you would give e.g. "Point to room and give directions to room".

Your role (please circle): Receptionist Nurse Doctor

Example question: …….. Patient/Companion - "*Where am I going next?*.....

Your response: ……Point to room and give directions to room……..……...

Question:.....
.....

Your response: ……..……...

Please continue overleaf.

Question:.....
.....

Your response: ……..……...

Question:.....
.....

Your response: ……..……...

2. What do you think a robot would be useful for? How would it help you best? For example, entertaining patients and companions, helping with form filling, doing time-consuming or repetitive tasks (please describe) and / or …????

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

……

……

……

……..

……..

……

……

3. The following are possible uses for the robot in the waiting room. Please rank them in order of usefulness **to you** (1 = most useful, 5 = least useful)

Robot use	Rank (1-5)
Welcoming patients - spot newcomers in the waiting room and let staff know.	
Check in/out support - help filling out forms, provide information on appointments.	
Subsequent consultation assistance - help filling out forms, provide information on consultation agenda and legal rights.	
Patient guidance - show patients to their destination.	
Entertainment - provide entertainment to patients and companions while they wait for appointments.	

7.4 Annex 4. Information notes and consent forms for SPRING study

Annex 4.1. Translation of the information note and the consent form for standard participants

SPRING « Socially Pertinent Robot In Gerontological Healthcare »

(monocentric Study)

PARTICIPANT INFORMATION NOTE

Research coordinator (responsible for data processing)	**Contact details of the Data Protection Officers**	**Principal investigator**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe 38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	**DPO INRIA Anne Combe** Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 Anne.combe@inria.fr **DPO AP-HP Philippe Tourenne** Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

Dear Sir or Madam,

The research team at Broca Hospital (Assistance Publique Hôpitaux de Paris, AP-HP) is working on the design and evaluation of new technologies for the care of the elderly.

We invite you to participate in the SPRING study coordinated by the National Institute for Research in Computer Science and Automation (INRIA). This study is taking place at the Broca Day Care Hospital (54 rue Pascal, 75013) where you will have your medical consultation.

What are the objectives of the SPRING study?

The main objective of SPRING is to develop a Socially Assistive Robot (SAR) able to interact simultaneously with multiple persons and perform open-domain dialogues

in cluttered environments (Figure 1). The robot will offer various reception functions to the public of the day care hospital, it will accompany the team of professional who are already working there. Unlike most current robot, at the end of the project, the robot in this study will be able to chat with several people to assist them. We are also working to determine the best way to use the potential of the robot for hospital patients, their families and all caregivers and hospital staff.

Figure 1. Illustrations of the robot used in the SPRING study

What is the design of the study?

During your day care hospital appointment, scheduled for ……/……../……., you will be invited to chat with the robot and to use it as many times as you wish it. A researcher will be present throughout the day to help you discover the robot and answer your questions. The researcher will have access to the result of your last neuropsychological assessment carried out at the day care hospital.

The robot will offer you several form of help according to your requests: a) reception and information of the day care hospital, b) information of consultations, c) information of available services (toilet, entry, exit, cafeteria), d) distraction (health prevention videos, games and cognitive stimulation activities), e) guidance service in the day care hospital. A brief presentation of the robot is provided in Annex 1 (at the end of this information note).

During the entire period you will be in the waiting room of the day hospital, and during your specific interactions with the robot, you will be recorded by its cameras and microphones (see technical description of the robot in Annex 1). After your interactions, we will invite you to complete a satisfaction questionnaire. The personal data recorded during this study will be pseudonymized, that is to say that they will be processed so that they cannot be assigned to you without having to use an identification key. Only the research team at Broca Hospital will have access to this identification key.

What are the expected benefits of participating in this study?

You will not derive any personal benefit from your participation in this study. But, thanks to your participation, you are contributing to the development of technologies that will, in the long term, better orient, welcome, inform and entertain the public in hospitals. The robot would then constitute additional support for the users of the hospital and for those who work there.

What data is saved?

The data collected for the realization of this study include on the one hand, “non-medical data": audiovisual recordings necessary for the robot to speak with you and move around within the day care hospital, the answers you will give to investigators' questionnaires, as well as "medical data": information from your neuropsychological assessment carried out at the day hospital of Broca hospital.

Who get access to your data?

"Non-medical data", such as video and audio recordings made by the robot, are only available to SPRING project partners, located in countries of the European Union, Israel and Scotland. All partners have signed a contract stipulating that your data can only be used for research and development purposes, in strict compliance with the guidelines established by AP-HP. This non-medical data is shared with partners of the SPRING project according to secure transfer and storage protocols, validated by the Defense Security Officer of INRIA, in order to ensure the best conditions of confidentiality and security.

Your “medical data" is in no case transferred to anyone and will only be accessible to the AP-HP team.

What is the future of the data collected?

The data collected during the SPRING study will be used to improve the robot's computer programs in order to improve its social and verbal skills. For example, they will train the robot's ability to recognize human speech and produce suitable speech or improve its ability to move around in a public place.

Are there any risks associated with the study?

This study poses no direct risk to you.

What are your rights?

Your participation in this study is entirely free and voluntary. You are free to refuse or interrupt your participation in this study at any time without incurring any liability or prejudice for this fact and without having to justify yourself.

If you interrupt your participation, the data collected until your withdrawal will be used for the analysis of the study results and will be kept for 20 years, unless you object.

If you agree to participate in the study before the date of your appointment at Broca Hospital, and the day of your appointment you no longer wish to participate, you are free to change your mind. As the robot will, in all cases, be present in the waiting room of the day hospital in Broca, we will suggest that you either stay in the general waiting room, without using or speaking directly with the robot, or go to another room in which you will not see the robot and it will not be able to see or register you either.

Your participation in this study will not be paid.

This study is not exclusive, so you can participate in other research projects.

The non-medical data collected will remain confidential and may only be consulted under the responsibility of the principal investigator of the SPRING study, by persons duly authorized and subject to professional secrecy. Medical data will not be available to anyone outside the Broca's research team, under the supervision of the study's lead investigator.

At the end of the study and after analyzing the data, you will be able to be informed of the overall results through the investigator, as stipulated by article L1122-1 of the Public Health Code.

This study has been approved by the European Union Ethics Commission. The computer file used for this study is implemented in accordance with the Data Protection regulations (CNIL - law 78-17 of January 6, 1978 modified).

In addition, the provisions made by the European Data Protection Regulation (GDPR) guarantee you several rights. You can :

- ask to have access, to rectify, to receive in a digitally readable format or to erase the data concerning you;

- object to the collection and transmission of your data or limit the use of your data only to this study or to other specific situations;

- in case of disagreement, make a complaint to the National Commission for Data Protection, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS or on https://www.cnil.fr/webform/adresser-une-plainte ;

- You also have the right to data portability, erasure, limitation of processing or opposition to the transmission of data covered by professional secrecy, which may be used and processed in the context of this study.

These rights are exercised with the principal investigator of this study, in particular by expressing your written opposition, or by making a complaint to a supervisory authority.

After reading all this information, discussed all aspects with the person who offers the study, and after being given time to think, if you do not object to the search you will have to sign and date the form of non-objection lying following this letter.

Thank you in advance for the confidence you have shown in us. We remain at your disposal on 01 44 08 35 03 (SPRING study contact) for any further information concerning this study.

Professor Anne-Sophie Rigaud

Principal investigator of the SPRING study

Presentation of the robot used in the SPRING study

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

PROFILE VIEW	FRONT VIEW	PHYSICAL CHARACTERISTICS
		• Height: 1.59 m • Weight: 59.8 kg • Moves while rolling • Articulated arms (cannot carry anything) **INTERFACE** • Touch pad • Animated eyes • Luminous ears **AUTONOMY** • 8 to 12 hours of battery **WiFi CONNECTIVITY** • Wired and wireless, Bluetooth **VISION** • 3 cameras (head, torso and back) **AUDIO** • 4 microphones

Non-opposition to research form. N °……

« SPRING »

« Socially Pertinent Robot In Gerontological Healthcare »

I, the undersigned: ……

Having the quality of

Patient within the hospital group "Hôpitaux Universitaire" Paris Center, on the Broca site

Legal representative in my capacity as …… (Title), Madam / Sir …… …… (name and surname), patient within the hospital group "Hôpitaux Universitaire" Paris Center, Broca site, freely accepts to participate in the research entitled: SPRING, organized by Hôpital Broca (APHP), under the scientific responsibility of Professor Anne-Sophie RIGAUD. As part of this study, I authorize the investigator to collect my data as defined in the information note above.

- I have read the information note for the SPRING study, explaining the purpose of this study, how it will be carried out and what my participation will involve.

- I received answers adapted to all my questions.

- I had enough time to make the decision to participate in this study.

- I understand that my participation is free and that I can interrupt it at any time, without incurring any liability or prejudice.

- I have understood my rights guaranteed by the GDPR with regard to the use of the data collected within the framework of this study.

- The non-opposition to my participation in no way discharges the principal investigator, nor the promoter (AP-HP), of all of their responsibilities and I retain all my rights guaranteed by law.

- I will keep an original copy of this information note.

Done at, the …… /… … / 202…,

Signature of the person participating in the experiment or their legal representative, preceded by the words "Read and approved"

I, the undersigned …… (investigator) certify that I have informed and received the non-opposition agreement of the above-mentioned person in accordance with the provisions of 3 ° of article L. 1121-1 of the Public Health Code.

Participant copy

A version of this form will also be signed for the principal investigator and the study coordinator.

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Annex 4.2. Information note and consent form for standard participants

SPRING « Socially Pertinent Robot In Gerontological Healthcare »
(Etude monocentrique)

NOTICE D'INFORMATION DU PARTICIPANT

Coordinateur de la recherche (responsable du traitement des données)	**Coordonnées des Délégués à la Protection des Données**	**Investigateur principal**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe 38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	**DPO INRIA Anne Combe** Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 anne.combe@inria.fr **DPO AP-HP Philippe Tourenne** Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

Madame, Monsieur,

Notre équipe de recherche de l'hôpital Broca (Assistance Publique Hôpitaux de Paris, AP-HP) travaille sur la conception et l'évaluation des nouvelles technologies pour la prise en charge des personnes âgées.

Nous vous proposons de participer à l'étude SPRING coordonnée par l'Institut National de Recherche en informatique et en Automatique (INRIA). Cette étude se déroule à l'hôpital de jour de l'hôpital Broca (54 rue Pascal, 75013) où vous aurez votre consultation médicale.

Quels sont les objectifs de l'étude SPRING ?

L'objectif de l'étude SPRING est de développer les capacités d'interaction d'un robot social d'accueil avec le public (Figure 1). Le robot proposera différentes fonctions d'accueil au public de l'hôpital du jour, il accompagnera l'équipe de professionnels qui y travaille déjà. Contrairement à la plupart des robots actuels, le robot de cette étude sera capable de discuter avec plusieurs personnes afin de les assister à la fin du projet. Nous cherchons également à déterminer les meilleures manières d'utiliser le potentiel de ce robot pour les patients de l'hôpital, leurs familles et l'ensemble des soignants et du personnel hospitalier.

Figure 1. Illustrations du robot utilisé dans l'étude SPRING

<u>En quoi consiste l'étude ?</u>

Lors de votre rendez-vous à l'hôpital de jour, prévu le ……./……../……., vous serez invité à discuter avec le robot et à l'utiliser à une ou plusieurs reprises en fonction de vos souhaits. Un chercheur sera présent tout au long de la journée pour vous accompagner dans la découverte du robot et répondre à vos questions. Le chercheur aura accès aux résultats de votre dernier bilan neuropsychologique réalisé à l'hôpital de jour.

Le robot vous proposera plusieurs formes d'aide en fonction de vos demandes : a) accueil et présentation de l'hôpital de jour, b) informations sur les consultations, c) informations sur les services disponibles (toilette, entrée, sortie, cafétéria), d) distractions (vidéos de prévention en santé, jeux et activités de stimulation cognitive), e) service de guidage pour vos déplacements à l'hôpital de jour. On vous invitera à essayer ces modalités d'échange ainsi que les différentes applications, à nous donner votre avis et à remplir un questionnaire de satisfaction. Une présentation succincte du robot est proposée en Annexe 1 (à la fin de cette note d'information).

Pendant toute la période où vous serez dans la salle d'attente de l'hôpital de jour, et pendant vos interactions spécifiques avec le robot, vous serez enregistré par ses caméras et microphones (voir description technique du robot en Annexe 1). À l'issue de vos interactions, nous vous inviterons à remplir un questionnaire de satisfaction. Les données personnelles enregistrées lors de cette étude seront pseudonymisées, c'est-à-dire qu'elles seront traitées de manière qu'on ne puisse pas les attribuer à vous même sans avoir recours à une clé d'identification. Seulement l'équipe de recherche de l'hôpital Broca aura accès à cette clé d'identification.

<u>Quels sont les bénéfices attendus liés à votre participation à cette étude ?</u>

Vous ne tirerez aucun bénéfice personnel de votre participation à cette étude. Mais, grâce à votre participation, vous contribuez au développement des technologies qui permettront, à terme, de mieux orienter, accueillir, informer et divertir le public dans les hôpitaux. Le robot constituerait alors un appui supplémentaire pour les usagers de l'hôpital et pour ceux qui y travaillent.

Quelles sont les données enregistrées ?

Les données collectées pour la réalisation de cette étude comportent d'une part, des « données non- médicales » : enregistrements audiovisuels nécessaires au robot pour parler avec vous et se déplacer au sein de l'hôpital de jour, les réponses que vous donnerez aux questionnaires des investigateurs, ainsi que des « données médicales » : informations de votre bilan neuropsychologique réalisé à l'hôpital du jour de l'hôpital Broca.

Qui a accès à vos données ?

Les « données non médicales », comme les enregistrements vidéo et audio faits par le robot, sont uniquement accessibles aux partenaires du projet SPRING, situés dans des pays de l'Union européenne, en Israël et en Écosse. Tous les partenaires ont signé un contrat stipulant que vos données ne peuvent être exploitées qu'à des fins de recherche et développement, dans le strict respect des consignes établies par l'AP-HP. Ces données non médicales sont transmises aux partenaires du projet SPRING selon des protocoles de transfert et de stockage sécurisés, validés par le Fonctionnaire Sécurité Défense de l'INRIA, afin d'assurer les meilleures conditions de confidentialité et de sécurité.

Vos « données médicales » ne sont en aucun cas transférées à qui que ce soit, et ne seront accessibles qu'à l'équipe de l'AP-HP.

Quelle utilisation sera faite des données recueillies ?

Les données collectées lors de l'étude SPRING serviront à améliorer les programmes informatiques nécessaires à la conception des interactions du robot d'accueil avec les usagers. Par exemple, elles permettront d'entraîner les capacités du robot à reconnaître la parole humaine et à produire un discours adapté ou à améliorer ses capacités de déplacement dans un lieu public.

Existe-t-il des risques associés à l'étude ?

Cette étude ne comporte aucun risque direct pour vous.

Quels sont vos droits ?

Votre participation à cette étude est entièrement **libre et volontaire**. Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier.

Si vous interrompez votre participation, les données collectées jusqu'à votre retrait seront utilisées pour l'analyse des résultats de l'étude et seront conservées pendant 20 ans, sauf opposition de votre part.

Si vous acceptez de participer à l'étude avant la date de votre rendez-vous à l'hôpital Broca, et que le jour même de votre rendez-vous vous ne souhaitez plus participer, vous est libre de changer d'avis. Comme le robot sera, dans tous les cas, présent dans la salle d'attente de l'hôpital de jour à Broca, nous vous proposerons, soit de rester dans la salle d'attente générale, sans utiliser ou parler directement avec le robot, soit d'aller dans une autre salle dans laquelle vous ne verrez pas le robot et celui-ci ne pourra pas non plus vous voir ni vous enregistrer.

Votre participation à cette étude ne sera pas rétribuée.

Cette étude n'est pas exclusive, vous pouvez donc participer à d'autres projets recherches.

Les données non médicales recueillies resteront confidentielles et ne pourront être consultées que sous la responsabilité de l'investigateur principal de l'étude SPRING, par des personnes dûment mandatées et soumises au secret professionnel. Les données médicales ne seront consultables par aucune personne en dehors de l'équipe de recherche de l'hôpital Broca, et ce sous la supervision de l'investigateur principal de l'étude.

À l'issue de l'étude et après analyse des données, vous pourrez être informé des résultats globaux par l'intermédiaire de l'investigateur, comme stipulé par l'article L1122-1 du Code de la Santé Publique.

Cette étude a reçu l'agrément de la commission éthique de l'Union européenne. Le fichier informatique utilisé pour cette étude est mis en œuvre conformément à la règlementation Informatique et Libertés (CNIL - loi 78-17 du 6 janvier 1978 modifiée).

De plus, les dispositions apportées par l'entrée en vigueur du Règlement Européen pour la Protection des Données (RGPD) vous garantissent plusieurs droits. Vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant ;
- vous opposer au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises ;
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur https://www.cnil.fr/webform/adresser-une-plainte ;
- Vous disposez également d'un droit de portabilité des données, d'effacement, de limitation de traitement ou d'opposition à la transmission des données couvertes par le secret professionnel, susceptibles d'être utilisées et traitées dans le cadre de cette étude.
- Ces droits s'exercent auprès de l'investigateur principal de cette étude, notamment en manifestant votre opposition écrite, ou en faisant une réclamation auprès d'une autorité de contrôle.

Après avoir lu toutes ces informations, discuté tous les aspects avec la personne qui vous propose l'étude, et après avoir bénéficié d'un temps de réflexion,

si vous ne vous opposez pas à la recherche vous devrez dater et signer le formulaire de non-opposition se trouvant à la suite de cette lettre.

Vous remerciant par avance de la confiance que vous nous témoignez, nous restons à votre disposition au 01 44 08 35 03 (contact étude SPRING) pour tout renseignement complémentaire concernant cette étude.

Professeur Anne-Sophie Rigaud

Investigateur principal de l'étude SPRING

Formulaire de non-opposition à la recherche N°

« SPRING »

« Socially Pertinent Robot In Gerontological Healthcare »

Je soussigné : .....

Ayant la qualité de

Patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca

Représentant légal en ma qualité de……(titre), de Madame /Monsieur…… (nom et prénom), patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca, accepte librement de participer à la recherche intitulée : SPRING, organisée par l'Hôpital Broca (APHP), sous la responsabilité scientifique du professeur Anne-Sophie RIGAUD. Dans le cadre de cette étude, j'autorise l'investigateur à recueillir les données me concernant, nécessaires à l'étude, comme défini dans la note d'information ci-dessus.

- J'ai pris connaissance de la note d'information de l'étude SPRING à destination des participants, m'expliquant l'objectif de cette étude, la façon dont elle va être réalisée et ce que ma participation va impliquer.
- J'ai reçu des réponses adaptées à toutes mes questions.
- J'ai disposé d'un temps suffisant pour prendre la décision de participer à cette étude.
- J'ai compris que ma participation est libre et que je pourrai l'interrompre à tout moment, sans encourir la moindre responsabilité ni préjudice.
- J'ai bien compris mes droits garantis par le RGPD quant à l'utilisation des données recueillies dans le cadre de cette étude.
- La non-opposition à ma participation ne décharge en rien l'investigateur principal, ni le promoteur (AP-HP), de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.
- Je conserverai un exemplaire original de la présente note d'information.

Fait à ..... , le ……/……/202… ,

Signature de la personne participant à l'expérimentation ou son représentant légal, précédée de la mention « Lu et approuvé »

Je soussigné(e)……(investigateur) certifie avoir informé et recueilli l'accord de non-opposition de la personne susmentionnée selon les dispositions du 3° de l'article L. 1121-1 du code de la santé Publique.

Exemplaire Participant

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

A version of this form will also be signed for the principal investigator and the study coordinator.

Annex 4.3. Information note and consent form for participants without specific data collection

SPRING « Socially Pertinent Robot In Gerontological Healthcare »

(Etude monocentrique)

NOTICE D'INFORMATION DU PARTICIPANT

Coordinateur de la recherche (responsable du traitement des données)	**Coordonnées des Délégués à la Protection des Données**	**Investigateur principal**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe 38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	**DPO INRIA Anne Combe** Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 anne.combe@inria.fr **DPO AP-HP Philippe Tourenne** Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

Madame, Monsieur,

Notre équipe de recherche de l'hôpital Broca (Assistance Publique Hôpitaux de Paris, AP-HP) travaille sur la conception et l'évaluation des nouvelles technologies pour la prise en charge des personnes âgées.

Nous réalisons actuellement l'étude SPRING coordonnée par l'Institut National de Recherche en Informatique et en Automatique (INRIA). Cette étude se déroule à l'hôpital de jour de l'hôpital Broca (54 rue Pascal, 75013) où vous aurez votre consultation médicale.

Quels sont les objectifs de l'étude SPRING ?

L'objectif de l'étude SPRING est de développer les capacités d'interaction d'un robot social d'accueil avec le public (Figure 1). Le robot proposera différentes fonctions d'accueil au public de l'hôpital du jour, il accompagnera l'équipe de professionnels qui y travaille déjà. Contrairement à la plupart des robots actuels, le robot de cette étude sera capable de discuter avec plusieurs personnes afin de les assister à la fin du projet. Nous cherchons également à déterminer les meilleures manières d'utiliser le potentiel de ce robot pour les patients de l'hôpital, leurs familles et l'ensemble des soignants et du personnel hospitalier.

Figure 1. Illustrations du robot utilisé dans l'étude SPRING

En quoi consiste l'étude ?

Lors de votre rendez-vous à l'hôpital de jour, prévu le ……./……../……., un robot sera présent dans la salle d'attente pour discuter avec d'autres personnes présentes dans la salle d'attente. Le robot leur proposera plusieurs formes d'aide en fonction des demandes : a) accueil et présentation de l'hôpital de jour, b) informations sur les consultations, c) informations sur les services disponibles (toilette, entrée, sortie, cafétéria), d) distractions (vidéos de prévention en santé, jeux et activités de stimulation cognitive), e) service de guidage pour les déplacements à l'hôpital de jour. Une présentation succincte du robot est proposée en Annexe 1 (à la fin de cette note d'information).

Pendant toute la période où vous serez dans la salle d'attente de l'hôpital de jour, vous pourrez être enregistré par ses caméras et microphones de manière non intentionnelle. Nous vous demandons donc votre autorisation pour être filmé et enregistré en tant que figurant. Nous ne vous demanderons rien d'autre dans le cadre de cette étude.

Les données personnelles enregistrées lors de cette étude seront pseudonymisées, c'est-à-dire qu'elles seront traitées de manière qu'on ne puisse pas les attribuer à vous même sans avoir recours à une clé d'identification. Seulement l'équipe de recherche de l'hôpital Broca aura accès à cette clé d'identification.

Quels sont les bénéfices attendus liés à votre participation à cette étude ?

Vous ne tirerez aucun bénéfice personnel de votre participation à cette étude. Par ailleurs, étant donné votre rôle de figurant dans la salle d'attente, vous n'interagirez pas directement avec le robot. Mais, grâce à votre participation, vous contribuez au développement des technologies qui permettront, à terme, de mieux orienter, accueillir, informer et divertir le public dans les hôpitaux. Le robot constituerait alors un appui supplémentaire pour les usagers de l'hôpital et pour ceux qui y travaillent.

Quelles sont les données enregistrées ?

Les données collectées pour la réalisation de cette étude vous concernant comportent exclusivement, des « données non- médicales » : enregistrements audiovisuels non-intentionnels, nécessaires au robot pour parler avec autres volontaires présents dans le même espace que vous et pour se déplacer au sein de l'hôpital de jour. Ces enregistrements sont non intentionnels dans votre cas puisque vous avez choisi de ne pas interagir directement avec le robot.

Qui a accès à vos données ?

Les données audio-visuelles vous concernant, enregistrées non-intentionnellement, seront uniquement accessibles aux partenaires du projet SPRING, situés dans des pays de l'Union européenne, en Israël et en Écosse. Tous les partenaires ont signé un contrat stipulant que vos données ne peuvent être exploitées qu'à des fins de recherche et développement, dans le strict respect des consignes établies par l'AP-HP. Ces données seront transmises aux partenaires du projet SPRING selon des protocoles de transfert et de stockage sécurisés, validés par le Fonctionnaire Sécurité Défense de l'INRIA, afin d'assurer les meilleures conditions de confidentialité et de sécurité.

Quelle utilisation sera faite des données recueillies ?

Les données collectées lors de l'étude SPRING serviront à améliorer les programmes informatiques nécessaires à la conception des interactions du robot d'accueil avec les usagers. Par exemple, elles permettront d'entraîner les capacités du robot à reconnaître la parole humaine et à produire un discours adapté ou à améliorer ses capacités de déplacement dans un lieu public.

Existe-t-il des risques associés à l'étude ?

Cette étude ne comporte aucun risque direct pour vous.

Quels sont vos droits ?

La participation à cette étude est entièrement **libre et volontaire**. Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier.

Si vous interrompez votre participation, les données collectées jusqu'à votre retrait seront utilisées pour l'analyse des résultats de l'étude et seront conservées pendant 20 ans, sauf opposition de votre part.

Si vous acceptez de participer à l'étude en tant que figurant avant la date de votre rendez-vous à l'hôpital Broca, et que le jour même de votre rendez-vous vous ne souhaitez plus participer, vous est libre de changer d'avis. Comme le robot sera, dans tous les cas, présent dans la salle d'attente de l'hôpital de jour à Broca, nous vous proposerons d'aller dans une autre salle dans laquelle vous ne verrez pas le robot et celui-ci ne pourra pas non plus vous voir ni vous enregistrer.

Votre participation à cette étude ne sera pas rétribuée.

Cette étude n'est pas exclusive, vous pouvez donc participer à d'autres projets recherches.

Les données non médicales recueillies resteront confidentielles et ne pourront être consultées que sous la responsabilité de l'investigateur principal de l'étude SPRING, par des personnes dûment mandatées et soumises au secret professionnel.

À l'issue de l'étude et après analyse des données, vous pourrez être informé des résultats globaux par l'intermédiaire de l'investigateur, comme stipulé par l'article L1122-1 du Code de la Santé Publique.

Cette étude a reçu l'agrément de la commission éthique de l'Union européenne. Le fichier informatique utilisé pour cette étude est mis en œuvre conformément à la règlementation Informatique et Libertés (CNIL - loi 78-17 du 6 janvier 1978 modifiée).

De plus, les dispositions apportées par l'entrée en vigueur du Règlement Européen pour la Protection des Données (RGPD) vous garantissent plusieurs droits. Vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant ;
- vous opposer au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises ;
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur https://www.cnil.fr/webform/adresser-une-plainte ;
- Vous disposez également d'un droit de portabilité des données, d'effacement, de limitation de traitement ou d'opposition à la transmission des données couvertes par le secret professionnel, susceptibles d'être utilisées et traitées dans le cadre de cette étude.

Ces droits s'exercent auprès de l'investigateur principal de cette étude, notamment en manifestant votre opposition écrite, ou en faisant une réclamation auprès d'une autorité de contrôle.

Après avoir lu toutes ces informations, discuté tous les aspects avec la personne qui vous propose l'étude, et après avoir bénéficié d'un temps de réflexion, si vous ne vous opposez pas à la recherche vous devrez dater et signer le formulaire de non-opposition se trouvant à la suite de cette lettre.

Vous remerciant par avance de la confiance que vous nous témoignez, nous restons à votre disposition au 01 44 08 35 03 (contact étude SPRING) pour tout renseignement complémentaire concernant cette étude.

Professeur Anne-Sophie Rigaud

Investigateur principal de l'étude SPRING

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Formulaire de non-opposition à la recherche N°

« SPRING »

« Socially Pertinent Robot In Gerontological Healthcare »

Je soussigné : .....

Ayant la qualité de

Patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca

Représentant légal en ma qualité de……(titre), de Madame /Monsieur…… (nom et prénom), patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca, accepte librement de participer à la recherche intitulée : SPRING, organisée par l'Hôpital Broca (APHP), sous la responsabilité scientifique du professeur Anne-Sophie RIGAUD. Dans le cadre de cette étude, j'autorise l'investigateur à recueillir les données me concernant, nécessaires à l'étude, comme défini dans la note d'information ci-dessus.

- J'ai pris connaissance de la note d'information de l'étude SPRING à destination des participants, m'expliquant l'objectif de cette étude, la façon dont elle va être réalisée et ce que ma participation va impliquer.
- J'ai reçu des réponses adaptées à toutes mes questions.
- J'ai disposé d'un temps suffisant pour prendre la décision de participer à cette étude.
- J'ai compris que ma participation est libre et que je pourrai l'interrompre à tout moment, sans encourir la moindre responsabilité ni préjudice.
- J'ai bien compris mes droits garantis par le RGPD quant à l'utilisation des données recueillies dans le cadre de cette étude.
- La non-opposition à ma participation ne décharge en rien le coordinateur de l'étude (INRIA) l'investigateur principal, ni le promoteur (AP-HP), de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.
- Je conserverai un exemplaire original de la présente note d'information.

Fait à ..... , le ……/……/202… ,

Signature de la personne participant à l'expérimentation ou son représentant légal, précédée de la mention « Lu et approuvé »

Je soussigné(e)……(investigateur) certifie avoir informé et recueilli l'accord de non-opposition de la personne susmentionnée selon les dispositions du 3° de l'article L. 1121-1 du code de la santé Publique.

Exemplaire Participant

A version of this form will also be signed for the principal investigator and the study coordinator.

Annex 4.4. Simplified information note and consent form for standard participants

"SPRING: Des robots sociaux pertinents dans les environnements de soin et de santé en gérontologie"

Madame, Monsieur,

L'équipe de recherche de l'hôpital Broca vous propose de participer à l'étude SPRING coordonnée par les chercheurs de l'INRIA Grenoble.

Quels sont les objectifs de l'étude SPRING ?

Le projet SPRING vise à développer un robot social d'accueil (voir figure 1), capable de discuter avec plusieurs personnes.

Nous cherchons également les meilleures manières d'utiliser ce robot à l'hôpital.

Figure 1. Illustrations du robot utilisé dans l'étude SPRING

En quoi consiste l'étude ?

Lors de votre rendez-vous, un chercheur vous accompagnera dans la découverte du robot. Vous pourrez lui poser des questions, choisir des activités ou lui demander des informations sur le déroulement de la journée.
Le robot enregistre votre voix et votre image pour vous répondre et se comporter avec le plus de naturel possible (voir une description du robot à la fin de cette notice d'information). Ces données font l'objet d'analyse par les ingénieurs de l'INRIA et ses partenaires pour améliorer le robot. Les chercheurs de Broca vous demanderont ensuite de nous donner votre avis sur ce robot.

Informations pratiques

L'expérimentation se déroulera pendant le temps d'attente de vos rendez-vous. Elle n'entravera pas le déroulement de votre journée à l'hôpital de Jour.

Risque : Il n'y a aucun risque à participer à cette recherche.
Elle est encadrée par la législation européenne et française et a reçu les agréments des institutions référentes.

Quels sont les bénéfices attendus liés à votre participation à cette étude ?

Vous ne tirerez aucun bénéfice personnel de votre participation à cette étude. Mais, grâce à votre participation, le robot pourrait orienter, informer et divertir le public. Il constituerait alors une aide pour les usagers de l'hôpital et les professionnels.

Quelles sont les données enregistrées ?

Les données enregistrées seront retranscrites et synthétisées en respectant votre identité. Elles sont traitées par les chercheurs de l'INRIA et leurs partenaires, tous engagés à travailler à des fins de recherches.

Quels sont vos droits ?

Conformément à la Loi n° 78-17 du 6 janvier 1978 relative à l'informatique et aux libertés, et au Règlement Européen n°2016/679 sur la Protection des Données, vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant
- vous opposez au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur https://www.cnil.fr/webform/adresser-une-plainte

Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier. En cas d'interruption de l'étude, les informations vous concernant seront conservées pendant 20 ans sauf opposition de votre part.

Si vous souhaitez des informations complémentaires, vous pouvez en parler avec la personne qui s'entretiendra avec vous.

Si vous acceptez de participer à cette étude, un formulaire de non-opposition à la recherche vous sera proposé pour signature à la suite de cette note d'information.

Vous remerciant par avance de la confiance que vous nous témoignez, nous restons à votre disposition au 01 44 08 35 03 (contact étude SPRING) pour tout renseignement complémentaire concernant cette étude.

Professeur Anne-Sophie Rigaud. Investigateur principal de l'étude SPRING

Personnes à contacter

Coordinateur de la recherche (responsable du traitement des données)	**Coordonnées des Délégués à la Protection des Données**	**Investigateur principal**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe	**DPO INRIA Anne Combe** Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 anne.combe@inria.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	**DPO AP-HP Philippe Tourenne** Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	

Formulaire de non-opposition à la recherche N°

« SPRING: Des robots sociaux pertinents dans les environnements de soin et de santé en gérontologie »

Je soussigné : .....
, ayant la qualité de

Patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca

Représentant légal en ma qualité de.....(titre), de Madame /Monsieur..... (nom et prénom), patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca, accepte librement de participer à la recherche intitulée : SPRING, organisée par l'Hôpital Broca (APHP), sous la responsabilité scientifique du professeur Anne-Sophie RIGAUD. Dans le cadre de cette étude, j'autorise l'investigateur à recueillir les données me concernant, nécessaires à l'étude, comme défini dans la note d'information ci-dessus.

- J'ai pris connaissance de la note d'information de l'étude SPRING à destination des participants, m'expliquant l'objectif de cette étude, la façon dont elle va être réalisée et ce que ma participation va impliquer.
- J'ai reçu des réponses adaptées à toutes mes questions.
- J'ai disposé d'un temps suffisant pour prendre la décision de participer à cette étude.
- J'ai compris que ma participation est libre et que je pourrai l'interrompre à tout moment, sans encourir la moindre responsabilité ni préjudice.
- J'ai bien compris mes droits garantis par le RGPD quant à l'utilisation des données recueillies dans le cadre de cette étude.
- La non-opposition à ma participation ne décharge en rien l'investigateur principal ni le promoteur (AP-HP), de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.
- Je conserverai un exemplaire original de la présente note d'information.

L'étude a été présentée oralement et par écrit de manière simplifiée et adaptée à Madame/Monsieur..... n'ayant manifesté aucune opposition, le représentant légal Madame/Monsieur..... autorise à ce qu'elle/il participe à cette recherche.

Fait à ..... , le ...../...../202... ,

Signature précédé de la mention « lu et approuvé »:

Je soussigné(e).....(investigateur) certifie avoir informé et recueilli l'accord de non-opposition de la personne susmentionnée selon les dispositions du 3° de l'article L. 1121-1 du code de la santé Publique.

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Exemplaire Participant

A version of this form will also be signed for the principal investigator and the study coordinator.

Annex 4.5. Simplified information note and consent form for participants without specific data collection

"SPRING : Des robots sociaux pertinents dans les environnements de soin et de santé en gérontologie"

Madame, Monsieur,

L'équipe de recherche de l'hôpital Broca réalise actuellement l'étude SPRING coordonnée par les chercheurs de l'INRIA Grenoble.

Quels sont les objectifs de l'étude SPRING ?

Le projet SPRING vise à développer un robot social d'accueil (voir figure 1), capable de se déplacer et de discuter avec les personnes.

Nous étudions les meilleures manières d'utiliser ce robot à l'hôpital.

Figure 1. Illustrations du robot utilisé dans l'étude SPRING

En quoi consiste l'étude ?

Pendant que vous êtes dans la salle d'attente, le robot discutera avec d'autres personnes et se déplacera dans la salle d'attente. Il est possible que le robot enregistre votre voix et votre image non intentionnellement à ce moment-là.
Nous vous demandons donc votre autorisation pour être filmé et enregistré en tant que figurant. Nous ne vous demanderons rien d'autre dans le cadre de cette étude.
Vous trouverez une description du robot à la fin de cette notice d'information.

Informations pratiques

L'expérimentation se déroulera pendant le temps d'attente de vos rendez-vous. Elle n'entravera pas le déroulement de votre journée à l'hôpital de Jour.

Risque : Il n'y a aucun risque à participer à cette recherche.
Elle est encadrée par la législation européenne et française et a reçu les agréments des institutions référentes.

Quels sont les bénéfices attendus liés à votre participation à cette étude ?

Vous ne tirerez aucun bénéfice personnel de votre participation à cette étude. Mais, grâce à votre participation, le robot pourrait orienter, informer et divertir le public. Il constituerait alors une aide pour les usagers de l'hôpital et les professionnels.

Quelles sont les données enregistrées ?

Les données enregistrées (image et audio) seront traitées en respectant votre identité par les chercheurs de l'INRIA et leurs partenaires, tous engagés à travailler à des fins de recherche.

Quels sont vos droits ?

Conformément à la Loi n° 78-17 du 6 janvier 1978 relative à l'informatique et aux libertés, et au Règlement Européen n°2016/679 sur la Protection des Données, vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant
- vous opposez au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur https://www.cnil.fr/webform/adresser-une-plainte

Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier. En cas d'interruption de l'étude, les informations vous concernant seront conservées pendant 20 ans sauf opposition de votre part.

Si vous souhaitez des informations complémentaires, vous pouvez en parler avec la personne qui s'entretiendra avec vous.

Si vous acceptez de participer à cette étude, un formulaire de non-opposition à la recherche vous sera proposé pour signature à la suite de cette note d'information.

Vous remerciant par avance de la confiance que vous nous témoignez, nous restons à votre disposition au 01 44 08 35 03 (contact étude SPRING) pour tout renseignement complémentaire concernant cette étude.

Professeur Anne-Sophie Rigaud. Investigateur principal de l'étude SPRING

Personnes à contacter

Coordinateur de la recherche (responsable du traitement des données)	**Coordonnées des Délégués à la Protection des Données**	**Investigateur principal**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe	**DPO INRIA Anne Combe** Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 Anne.combe@inria.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	**DPO AP-HP Philippe Tourenne** Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	

Formulaire de non-opposition à la recherche N°

« SPRING: Des robots sociaux pertinents dans les environnements de soin et de santé en gérontologie »

Je soussigné : .....

Ayant la qualité de

Patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca

Représentant légal en ma qualité de.....(titre), de Madame /Monsieur..... (nom et prénom), patient au sein du groupe hospitalier Hôpitaux Universitaire Paris Centre, site Broca, accepte librement de participer à la recherche intitulée : SPRING, organisée par l'Hôpital Broca (APHP), sous la responsabilité scientifique du professeur Anne-Sophie RIGAUD. Dans le cadre de cette étude, j'autorise l'investigateur à recueillir les données me concernant, nécessaires à l'étude, comme défini dans la note d'information ci-dessus.

- J'ai pris connaissance de la note d'information de l'étude SPRING à destination des participants, m'expliquant l'objectif de cette étude, la façon dont elle va être réalisée et ce que ma participation va impliquer.

- J'ai reçu des réponses adaptées à toutes mes questions.

- J'ai disposé d'un temps suffisant pour prendre la décision de participer à cette étude.

- J'ai compris que ma participation est libre et que je pourrai l'interrompre à tout moment, sans encourir la moindre responsabilité ni préjudice.

- J'ai bien compris mes droits garantis par le RGPD quant à l'utilisation des données recueillies dans le cadre de cette étude.

- La non-opposition à ma participation ne décharge en rien l'investigateur principal ni le promoteur (AP-HP), de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.

- Je conserverai un exemplaire original de la présente note d'information.

L'étude a été présentée oralement et par écrit de manière simplifiée et adaptée à Madame/Monsieur..... n'ayant manifesté aucune opposition, le représentant légal Madame/Monsieur..... autorise à ce qu'elle/il participe à cette recherche.

Fait à ..... , le ...../...../202... ,

Signature précédé de la mention « lu et approuvé »:

Je soussigné(e)……..(investigateur) certifie avoir informé et recueilli l'accord de non-opposition de la personne susmentionnée selon les dispositions du 3° de l'article L. 1121-1 du code de la santé Publique.

Exemplaire Participant

A version of this form will also be signed for the principal investigator and the study coordinator.

Annex 4.6. Information note and consent form for professionals

SPRING « Socially Pertinent Robot In Gerontological Healthcare »

(Etude monocentrique)

NOTICE D'INFORMATION DU PARTICIPANT PROFESSIONNEL

Coordinateur de la recherche (responsable du traitement des données)	**Coordonnées des Délégués à la Protection des Données**	**Investigateur principal**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe 38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	DPO INRIA Anne Combe Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 anne.combe@inria.fr DPO AP-HP Philippe Tourenne Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

Madame, Monsieur,

Notre équipe de recherche de l'hôpital Broca (Assistance Publique Hôpitaux de Paris, AP-HP) travaille sur la conception et l'évaluation des nouvelles technologies pour la prise en charge des personnes âgées.

Nous vous proposons de participer à l'**étude SPRING** coordonnée par *l'Institut National de Recherche en informatique et en Automatique* (INRIA). Cette étude se déroule à l'hôpital de jour de l'hôpital Broca (54 rue Pascal, 75013).

Quels sont les objectifs de l'étude SPRING ?

L'objectif de l'étude SPRING est de développer les capacités d'interaction d'un robot social d'accueil avec le public (Figure 1). Le robot proposera différentes fonctions d'accueil au public de l'hôpital du jour, en accompagnement du travail des professionnels. Contrairement à la plupart des robots actuels, le robot de cette étude sera capable de discuter avec plusieurs personnes afin de les assister à la fin du projet. Nous cherchons également à déterminer les meilleures manières d'utiliser le potentiel de ce robot pour les patients de l'hôpital, leurs familles et l'ensemble des soignants et du personnel hospitalier.

Figure 1. Illustrations du robot utilisé dans l'étude SPRING

<u>En quoi consiste l'étude ?</u>

Cette étude se déroule sur une période de 12 mois. Le robot sera présent à l'hôpital de jour 2 fois par mois. Lors de l'exercice de votre travail pendant les jours de présence du robot, vous serez invité à discuter avec celui-ci et à l'utiliser à une ou plusieurs reprises en fonction de vos souhaits. Un chercheur sera présent tout au long de la journée pour vous accompagner dans la découverte du robot et répondre à vos questions.

Le robot vous proposera plusieurs formes d'aide en fonction des demandes des participants : a) accueil et présentation de l'hôpital de jour, b) informations sur les consultations, c) informations sur les services disponibles (toilette, entrée, sortie, cafétéria), d) distractions (vidéos de prévention en santé, jeux et activités de stimulation cognitive), e) service de guidage pour leurs déplacements à l'hôpital de jour. On vous invitera à essayer ces modalités d'échange ainsi que les différentes applications, à nous donner votre avis et à remplir un questionnaire de satisfaction. Une présentation succincte du robot est proposée en Annexe 1 (à la fin de cette note d'information).

Pendant toute la période où vous serez dans la salle d'attente de l'hôpital de jour, et pendant vos interactions spécifiques avec le robot, vous serez enregistré par ses caméras et microphones (voir description technique du robot en Annexe 1). Les données personnelles enregistrées lors de cette étude seront pseudonymisées, c'est-à-dire qu'elles seront traitées de manière qu'on ne puisse pas les attribuer à vous même sans avoir recours à une clé d'identification. Seulement l'équipe de recherche de l'hôpital Broca aura accès à cette clé d'identification.

Enfin, pendant toute la durée de l'étude, vous serez invité à plusieurs occasions à participer à des entretiens semi-structurés individuels ou collectifs ou à des focus groupes, cette participation sera totalement volontaire. Les dates de ces rencontres vous seront communiquées à l'avance.

Quels sont les bénéfices attendus liés à votre participation à cette étude ?

Vous ne tirerez aucun bénéfice personnel de votre participation à cette étude. Mais, grâce à votre participation, vous contribuez au développement des technologies qui permettront, à terme, de mieux orienter, accueillir, informer et divertir le public dans les hôpitaux. Le robot constituerait alors un appui supplémentaire pour les usagers de l'hôpital et pour ceux qui y travaillent.

Quelles sont les données enregistrées ?

Les données collectées pour la réalisation de cette étude vous concernant sont exclusivement des « données non médicales » : des enregistrements audiovisuels nécessaires au robot pour parler avec vous et se déplacer au sein de l'hôpital de jour et les réponses que vous donnerez aux questionnaires, entretiens semi-structurés ou focus groupes, si vous décidez d'y participer.

Qui a accès à vos données ?

Les données recueillies, comme les enregistrements vidéo et audio faits par le robot, sont uniquement accessibles aux partenaires du projet SPRING, situés dans des pays de l'Union européenne, en Israël et en Écosse. Tous les partenaires ont signé un contrat stipulant que vos données ne peuvent être exploitées qu'à des fins de recherche et développement, dans le strict respect des consignes établies par l'AP-HP. Ces données seront transmises aux partenaires du projet SPRING selon des protocoles de transfert et de stockage sécurisés, validés par le Fonctionnaire Sécurité Défense de l'INRIA, afin d'assurer les meilleures conditions de confidentialité et de sécurité.

Quelle utilisation sera faite des données recueillies ?

Les données collectées lors de l'étude SPRING serviront à améliorer les programmes informatiques nécessaires à la conception des interactions du robot d'accueil avec les usagers. Par exemple, elles permettront d'entraîner les capacités du robot à reconnaître la parole humaine et à produire un discours adapté ou à améliorer ses capacités de déplacement dans un lieu public. Les données collectées permettront également à déterminer les usages de ce type de robot dans un service hospitalier.

Existe-t-il des risques associés à l'étude ?

Cette étude ne comporte aucun risque direct pour vous.

Quels sont vos droits ?

Votre participation à cette étude est entièrement **libre et volontaire**. Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans

encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier.

Si vous interrompez votre participation, les données collectées jusqu'à votre retrait seront utilisées pour l'analyse des résultats de l'étude et seront conservées pendant 20 ans, sauf opposition de votre part.

Votre participation à cette étude ne sera pas rétribuée.

Cette étude n'est pas exclusive, vous pouvez donc participer à d'autres projets recherches.

Les données recueillies resteront confidentielles et ne pourront être consultées que sous la responsabilité de l'investigateur principal de l'étude SPRING, par des personnes dûment mandatées et soumises au secret professionnel.

À l'issue de l'étude et après analyse des données, vous pourrez être informé des résultats globaux par l'intermédiaire de l'investigateur, comme stipulé par l'article L1122-1 du Code de la Santé Publique.

Cette étude a reçu l'agrément de la commission éthique de l'Union européenne. Le fichier informatique utilisé pour cette étude est mis en œuvre conformément à la règlementation Informatique et Libertés (CNIL - loi 78-17 du 6 janvier 1978 modifiée).

De plus, les dispositions apportées par l'entrée en vigueur du Règlement Européen pour la Protection des Données (RGPD) vous garantissent plusieurs droits. Vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant ;
- vous opposer au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises ;
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur https://www.cnil.fr/webform/adresser-une-plainte ;
- Vous disposez également d'un droit de portabilité des données, d'effacement, de limitation de traitement ou d'opposition à la transmission des données couvertes par le secret professionnel, susceptibles d'être utilisées et traitées dans le cadre de cette étude.

Ces droits s'exercent auprès de l'investigateur principal de cette étude, notamment en manifestant votre opposition écrite, ou en faisant une réclamation auprès d'une autorité de contrôle.

Après avoir lu toutes ces informations, discuté tous les aspects avec la personne qui vous propose l'étude, et après avoir bénéficié d'un temps de réflexion, si vous ne vous opposez pas à la recherche vous devrez dater et signer le formulaire de non-opposition se trouvant à la suite de cette lettre.

Vous remerciant par avance de la confiance que vous nous témoignez, nous restons à votre disposition au 01 44 08 35 03 (contact étude SPRING) pour tout renseignement complémentaire concernant cette étude.

Professeur Anne-Sophie Rigaud

Investigateur principal de l'étude SPRING

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Formulaire de non-opposition à la recherche N°

« SPRING »

« Socially Pertinent Robot In Gerontological Healthcare »

Je soussigné : ..... (Nom,prénom)
……

Accepte librement de participer à la recherche intitulée : SPRING, Organisée par l'Hôpital Broca (APHP), sous la responsabilité scientifique du professeur Anne-Sophie RIGAUD. Dans le cadre de cette étude, j'autorise l'investigateur à recueillir les données me concernant, nécessaires à l'étude, comme défini dans la note d'information ci-dessus.

- J'ai pris connaissance de la note d'information de l'étude SPRING à destination des participants, m'expliquant l'objectif de cette étude, la façon dont elle va être réalisée et ce que ma participation va impliquer.

- J'ai reçu des réponses adaptées à toutes mes questions.

- J'ai disposé d'un temps suffisant pour prendre la décision de participer à cette étude.

- J'ai compris que ma participation est libre et que je pourrai y mettre fin à tout moment, sans que cela n'ait aucune conséquence.

- J'ai bien compris mes droits garantis quant à l'utilisation des données recueillies dans le cadre de cette étude.

- La non-opposition à ma participation ne décharge en rien le coordinateur de l'étude, l'investigateur principal, ni le promoteur (AP-HP), de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.

- Je conserverai un exemplaire original de la présente note d'information et du formulaire de consentement.

Fait à ..... , le ……/……./202… ,

Signature de la personne participant à l'expérimentation, précédée de la mention « Lu et approuvé »

Je soussigné(e)……..(investigateur) certifie avoir informé et recueilli l'accord de non-opposition de la personne susmentionnée selon les dispositions du 3° de l'article L. 1121-1 du code de la santé Publique.

Exemplaire Participant

A version of this form will also be signed for the principal investigator and the study coordinator.

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Annex 4.7. Information note and consent form for professional without specific data

SPRING « Socially Pertinent Robot In Gerontological Healthcare »

(Etude monocentrique)

NOTICE D'INFORMATION DU PARTICIPANT

Coordinateur de la recherche (responsable du traitement des données)	**Coordonnées des Délégués à la Protection des Données**	**Investigateur principal**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe 38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	DPO INRIA Anne Combe Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 anne.combe@inria.fr DPO AP-HP Philippe Tourenne Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

Madame, Monsieur,

Notre équipe de recherche de l'hôpital Broca (Assistance Publique Hôpitaux de Paris, AP-HP) travaille sur la conception et l'évaluation des nouvelles technologies pour la prise en charge des personnes âgées.

Nous réalisons actuellement l'**étude SPRING** coordonnée par *l'Institut National de Recherche en informatique et en Automatique* (INRIA). Cette étude se déroule à l'hôpital de jour de l'hôpital Broca (54 rue Pascal, 75013).

Quels sont les objectifs de l'étude SPRING ?

L'objectif de l'étude SPRING est de développer les capacités d'interaction d'un robot social d'accueil avec le public (Figure 1). Le robot proposera différentes fonctions d'accueil au public de l'hôpital du jour, en accompagnement du travail des professionnels. Contrairement à la plupart des robots actuels, le robot de cette étude sera capable de discuter avec plusieurs personnes afin de les assister à la fin du projet. Nous cherchons également à déterminer les meilleures manières d'utiliser le potentiel de ce robot pour les patients de l'hôpital, leurs familles et l'ensemble des soignants et du personnel hospitalier.

Figure 1. Illustrations du robot utilisé dans l'étude SPRING

<u>En quoi consiste l'étude ?</u>

Cette étude se déroule sur une période de 12 mois. Le robot sera présent à l'hôpital de jour 2 fois par mois. Lors de l'exercice de votre travail, les participants volontaires seront invités à discuter avec le robot et à l'utiliser à une ou plusieurs reprises en fonction de leurs souhaits. Un chercheur sera présent tout au long de la journée pour les accompagner dans la découverte du robot et répondre à leurs questions.

Le robot proposera plusieurs formes d'aide en fonction des demandes des participants : a) accueil et présentation de l'hôpital de jour, b) informations sur les consultations, c) informations sur les services disponibles (toilette, entrée, sortie, cafétéria), d) distractions (vidéos de prévention en santé, jeux et activités de stimulation cognitive), e) service de guidage pour leurs déplacements à l'hôpital de jour. Une présentation succincte du robot est proposée en Annexe 1 (à la fin de cette note d'information).

Pendant toute la période où vous serez dans la salle d'attente de l'hôpital de jour, vous serez enregistré par les caméras et microphones du robot de manière non intentionnelle. Nous vous demandons donc votre autorisation pour être filmé et enregistré en tant que figurant. Nous ne vous demandons rien d'autre dans le cadre de cette étude.

Les données personnelles enregistrées lors de cette étude seront pseudonymisées, c'est-à-dire qu'elles seront traitées de manière qu'on ne puisse pas les attribuer à vous même sans avoir recours à une clé d'identification. Seulement l'équipe de recherche de l'hôpital Broca aura accès à cette clé d'identification.

<u>Quels sont les bénéfices attendus liés à votre participation à cette étude ?</u>

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 871245.

Vous ne tirerez aucun bénéfice personnel de votre participation à cette étude. Par ailleurs, étant donné votre rôle de figurant lors de cette étude, vous n'interagirez pas directement avec le robot. Mais, grâce à votre participation, vous contribuez au développement des technologies qui permettront, à terme, de mieux orienter, accueillir, informer et divertir le public dans les hôpitaux. Le robot constituerait alors un appui supplémentaire pour les usagers de l'hôpital et pour ceux qui y travaillent.

Quelles sont les données enregistrées ?

Les données collectées pour la réalisation de cette étude comportent des « données non- médicales » : enregistrements audiovisuels nécessaires au robot pour parler avec les participants et se déplacer au sein de l'hôpital de jour. Ces enregistrements sont non intentionnels dans votre cas puisque vous avez choisi de ne pas interagir directement avec le robot.

Qui a accès à vos données ?

Les « données non médicales », comme les enregistrements vidéo et audio faits par le robot, sont uniquement accessibles aux partenaires du projet SPRING, situés dans des pays de l'Union européenne, en Israël et en Écosse. Tous les partenaires ont signé un contrat stipulant que vos données ne peuvent être exploitées qu'à des fins de recherche et développement, dans le strict respect des consignes établies par l'AP-HP. Ces données non médicales sont transmises aux partenaires du projet SPRING selon des protocoles de transfert et de stockage sécurisés, validés par le Fonctionnaire Sécurité Défense de l'INRIA, afin d'assurer les meilleures conditions de confidentialité et de sécurité.

Quelle utilisation sera faite des données recueillies ?

Les données collectées lors de l'étude SPRING serviront à améliorer les programmes informatiques nécessaires à la conception des interactions du robot d'accueil avec les usagers. Par exemple, elles permettront d'entraîner les capacités du robot à reconnaître la parole humaine et à produire un discours adapté ou à améliorer ses capacités de déplacement dans un lieu public. Les données collectées permettront également à déterminer les usages de ce type de robot dans un service hospitalier.

Existe-t-il des risques associés à l'étude ?

Cette étude ne comporte aucun risque direct pour vous.

Quels sont vos droits ?

Votre participation à cette étude est entièrement **libre et volontaire**. Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier.

Si vous interrompez votre participation, les données collectées jusqu'à votre retrait seront utilisées pour l'analyse des résultats de l'étude et seront conservées pendant 20 ans, sauf opposition de votre part.

Votre participation à cette étude ne sera pas rétribuée.

Cette étude n'est pas exclusive, vous pouvez donc participer à d'autres projets recherches.

Les données non médicales recueillies resteront confidentielles et ne pourront être consultées que sous la responsabilité de l'investigateur principal de l'étude SPRING, par des personnes dûment mandatées et soumises au secret professionnel.

À l'issue de l'étude et après analyse des données, vous pourrez être informé des résultats globaux par l'intermédiaire de l'investigateur, comme stipulé par l'article L1122-1 du Code de la Santé Publique.

Cette étude a reçu l'agrément de la commission éthique de l'Union européenne. Le fichier informatique utilisé pour cette étude est mis en œuvre conformément à la règlementation Informatique et Libertés (CNIL - loi 78-17 du 6 janvier 1978 modifiée).

De plus, les dispositions apportées par l'entrée en vigueur du Règlement Européen pour la Protection des Données (RGPD) vous garantissent plusieurs droits. Vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant ;
- vous opposer au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises ;
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur https://www.cnil.fr/webform/adresser-une-plainte ;
- Vous disposez également d'un droit de portabilité des données, d'effacement, de limitation de traitement ou d'opposition à la transmission des données couvertes par le secret professionnel, susceptibles d'être utilisées et traitées dans le cadre de cette étude.

Ces droits s'exercent auprès de l'investigateur principal de cette étude, notamment en manifestant votre opposition écrite, ou en faisant une réclamation auprès d'une autorité de contrôle.

Après avoir lu toutes ces informations, discuté tous les aspects avec la personne qui vous propose l'étude, et après avoir bénéficié d'un temps de réflexion, si vous ne vous opposez pas à la recherche vous devrez dater et signer le formulaire de non-opposition se trouvant à la suite de cette lettre.

Vous remerciant par avance de la confiance que vous nous témoignez, nous restons à votre disposition au 01 44 08 35 03 (contact étude SPRING) pour tout renseignement complémentaire concernant cette étude.

Professeur Anne-Sophie Rigaud

Investigateur principal de l'étude SPRING

Formulaire de non-opposition à la recherche N°

« SPRING »

« Socially Pertinent Robot In Gerontological Healthcare »

Je soussigné : .....

Accepte librement de participer à la recherche intitulée : SPRING, organisée par l'Hôpital Broca (APHP), sous la responsabilité scientifique du professeur Anne-Sophie RIGAUD. Dans le cadre de cette étude, j'autorise l'investigateur à recueillir les données me concernant, nécessaires à l'étude, comme défini dans la note d'information ci-dessus.

- J'ai pris connaissance de la note d'information de l'étude SPRING à destination des participants, m'expliquant l'objectif de cette étude, la façon dont elle va être réalisée et ce que ma participation va impliquer.
- J'ai reçu des réponses adaptées à toutes mes questions.
- J'ai disposé d'un temps suffisant pour prendre la décision de participer à cette étude.
- J'ai compris que ma participation est libre et que je pourrai l'interrompre à tout moment, sans encourir la moindre responsabilité ni préjudice.
- J'ai bien été informé(e) que ma participation à cette recherche sera étendue sur une période de 12 mois et le robot sera présent à l'hôpital de jour environs deux fois par mois.
- J'ai bien compris mes droits garantis par le RGPD quant à l'utilisation des données recueillies dans le cadre de cette étude.
- La non-opposition à ma participation ne décharge en rien le coordinateur de l'étude, l'investigateur principal, ni le promoteur (AP-HP), de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.
- Je conserverai un exemplaire original de la présente note d'information.

Fait à ..... , le ...../...../202... ,

Signature de la personne participant à l'expérimentation, précédée de la mention « Lu et approuvé »

Je soussigné(e).....(investigateur) certifie avoir informé et recueilli l'accord de non-opposition de la personne susmentionnée selon les dispositions du 3° de l'article L. 1121-1 du code de la santé Publique.

Exemplaire Participant

A version of this form will also be signed for the principal investigator and the study coordinator.

Annex 4.8. Information note and consent form for simulation experiment participants

SPRING « Socially Pertinent Robot In Gerontological Healthcare »

(Etude monocentrique)

NOTICE D'INFORMATION DU PARTICIPANT

Coordinateur de la recherche (responsable du traitement des données)	**Coordonnées des Délégués à la Protection des Données**	**Investigateur principal**
Xavier Alameda-Pineda INRIA 655 avenue de l'Europe 38330 Montbonnot-Saint-Martin 04 76 61 52 08 xavier.alameda-pineda@inria.fr	**DPO INRIA Anne Combe** Centre de recherche INRIA Sophia Antipolis – Méditerranée 2004 route des Lucioles 06902 Valbonne 04 92 38 71 73 anne.combe@inria.fr **DPO AP-HP Philippe Tourenne** Direction du Système d'Information Référent protection des données Hôpitaux Necker - Cochin – Hôtel-Dieu – Broca 27, rue du Faubourg St Jacques 75 678 Paris Cedex 14 01 58 41 12 87 philippe.tourenne@aphp.fr	Professeur Anne-Sophie Rigaud Hôpital Broca 54-56 Rue Pascal 75013 Paris 01 44 08 35 03 anne-sophie.rigaud@aphp.fr

Madame, Monsieur,

Notre équipe de recherche de l'hôpital Broca (Assistance Publique Hôpitaux de Paris, AP-HP) travaille sur la conception et l'évaluation des nouvelles technologies pour la prise en charge des personnes âgées.

Nous vous proposons de participer à l'**étude SPRING** coordonnée par *l'Institut National de Recherche en informatique et en Automatique* (INRIA). Cette étude se déroule dans le living lab de l'hôpital Broca (54 rue Pascal, 75013, bâtiment bleu au fond du jardin).

Quels sont les objectifs de l'étude SPRING ?

L'objectif de l'étude SPRING est de développer les capacités d'interaction d'un robot social d'accueil avec le public (Figure 1). A terme, le robot proposera différentes fonctions d'accueil au public de l'hôpital du jour, il accompagnera l'équipe de professionnels qui y travaille déjà. Contrairement à la plupart des robots actuels, le robot de cette étude sera capable de discuter avec plusieurs personnes afin de les assister à la fin du projet. Nous cherchons également à déterminer les meilleures manières d'utiliser le potentiel de ce robot pour les patients de l'hôpital, leurs familles et l'ensemble des soignants et du personnel hospitalier.

Figure 1. Illustrations du robot utilisé dans l'étude SPRING

<u>En quoi consiste l'étude ?</u>

Lors de votre rendez-vous au Broca Living Lab, **prévu le ……./……../……..,** vous serez invité à discuter avec le robot et à l'utiliser à une ou plusieurs reprises en fonction de vos souhaits. Un chercheur sera présent tout au long de la journée pour vous accompagner dans la découverte du robot et répondre à vos questions.

Le robot vous proposera plusieurs formes d'échanges : a) accueil et présentation de l'hôpital de jour, b) informations sur les consultations, c) informations sur les services disponibles (toilette, entrée, sortie, cafétéria), d) distractions (vidéos de prévention en santé, jeux et activités de stimulation cognitive), e) service de guidage pour les déplacements. On vous invitera à essayer ces modalités d'échange ainsi que les différentes applications et à nous donner votre avis. Votre participation à cette expérience aura une durée d'environ 1h30. Une présentation succincte du robot est proposée en Annexe 1 (à la fin de cette note d'information).

Pendant vos interactions spécifiques avec le robot, vous serez enregistré par ses caméras et microphones (voir description technique du robot en Annexe 1). À l'issue de vos interactions, nous vous inviterons à remplir un questionnaire de satisfaction. Les données personnelles enregistrées lors de cette étude seront pseudonymisées, c'est-à-dire qu'elles seront traitées de manière qu'on ne puisse pas les attribuer à vous même sans avoir recours à une clé d'identification. Seulement l'équipe de recherche de l'hôpital Broca aura accès à cette clé d'identification.

<u>Quels sont les bénéfices attendus liés à votre participation à cette étude ?</u>

Vous ne tirerez aucun bénéfice personnel de votre participation à cette étude. Mais, grâce à votre participation, vous contribuez au développement des technologies qui permettront, à terme, de mieux orienter, accueillir, informer et divertir

le public dans les hôpitaux. Le robot constituerait alors un appui supplémentaire pour les usagers de l'hôpital et pour ceux qui y travaillent.

Quelles sont les données enregistrées ?

Les données collectées pour la réalisation de cette étude comportent, des « données non- médicales » : enregistrements audiovisuels nécessaires au robot pour parler avec vous et se déplacer, ainsi que les réponses que vous donnerez aux questionnaires des investigateurs.

Qui a accès à vos données ?

Les « données non médicales », comme les enregistrements vidéo et audio faits par le robot, sont uniquement accessibles aux partenaires du projet SPRING, situés dans des pays de l'Union européenne, en Israël et en Écosse. Tous les partenaires ont signé un contrat stipulant que vos données ne peuvent être exploitées qu'à des fins de recherche et développement, dans le strict respect des consignes établies par l'AP-HP. Ces données non médicales sont transmises aux partenaires du projet SPRING selon des protocoles de transfert et de stockage sécurisés, validés par le Fonctionnaire Sécurité Défense de l'INRIA, afin d'assurer les meilleures conditions de confidentialité et de sécurité.

Quelle utilisation sera faite des données recueillies ?

Les données collectées lors de l'étude SPRING serviront à améliorer les programmes informatiques nécessaires à la conception des interactions du robot d'accueil avec les usagers. Par exemple, elles permettront d'entraîner les capacités du robot à reconnaître la parole humaine et à produire un discours adapté ou à améliorer ses capacités de déplacement dans un lieu public.

Existe-t-il des risques associés à l'étude ?

Cette étude ne comporte aucun risque direct pour vous.

Quels sont vos droits ?

Votre participation à cette étude est entièrement **libre et volontaire**. Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier.

Si vous interrompez votre participation, les données collectées jusqu'à votre retrait seront utilisées pour l'analyse des résultats de l'étude et seront conservées pendant 20 ans, sauf opposition de votre part.

Si vous acceptez de participer à l'étude avant la date de votre rendez-vous au Broca Living Lab, et que le jour même de votre rendez-vous vous ne souhaitez plus participer, vous est libre de changer d'avis.

Votre participation à cette étude ne sera pas rétribuée.

Cette étude n'est pas exclusive, vous pouvez donc participer à d'autres projets recherches.

Les données non médicales recueillies resteront confidentielles et ne pourront être consultées que sous la responsabilité de l'investigateur principal de l'étude SPRING, par des personnes dûment mandatées et soumises au secret professionnel.

À l'issue de l'étude et après analyse des données, vous pourrez être informé des résultats globaux par l'intermédiaire de l'investigateur, comme stipulé par l'article L1122-1 du Code de la Santé Publique.

Cette étude a reçu l'agrément de la commission éthique de l'Union européenne. Le fichier informatique utilisé pour cette étude est mis en œuvre conformément à la règlementation Informatique et Libertés (CNIL - loi 78-17 du 6 janvier 1978 modifiée).

De plus, les dispositions apportées par l'entrée en vigueur du Règlement Européen pour la Protection des Données (RGPD) vous garantissent plusieurs droits. Vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant ;
- vous opposer au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises ;
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur https://www.cnil.fr/webform/adresser-une-plainte ;
- Vous disposez également d'un droit de portabilité des données, d'effacement, de limitation de traitement ou d'opposition à la transmission des données couvertes par le secret professionnel, susceptibles d'être utilisées et traitées dans le cadre de cette étude.

Ces droits s'exercent auprès de l'investigateur principal de cette étude, notamment en manifestant votre opposition écrite, ou en faisant une réclamation auprès d'une autorité de contrôle.

Après avoir lu toutes ces informations, discuté tous les aspects avec la personne qui vous propose l'étude, et après avoir bénéficié d'un temps de réflexion, si vous ne vous opposez pas à la recherche vous devrez dater et signer le formulaire de non-opposition se trouvant à la suite de cette lettre.

Vous remerciant par avance de la confiance que vous nous témoignez, nous restons à votre disposition au 01 44 08 35 03 (contact étude SPRING) pour tout renseignement complémentaire concernant cette étude.

Professeur Anne-Sophie Rigaud

Investigateur principal de l'étude SPRING

Formulaire de non-opposition à la recherche N°

« SPRING »

« Socially Pertinent Robot In Gerontological Healthcare »

Je soussigné : ..... (Nom,prénom)
……

Accepte librement de participer à la recherche intitulée : SPRING, organisée par l'Hôpital Broca (APHP), sous la responsabilité scientifique du professeur Anne-Sophie RIGAUD. Dans le cadre de cette étude, j'autorise l'investigateur à recueillir les données me concernant, nécessaires à l'étude, comme défini dans la note d'information ci-dessus.

- J'ai pris connaissance de la note d'information de l'étude SPRING à destination des participants, m'expliquant l'objectif de cette étude, la façon dont elle va être réalisée et ce que ma participation va impliquer.

- J'ai reçu des réponses adaptées à toutes mes questions.

- J'ai disposé d'un temps suffisant pour prendre la décision de participer à cette étude.

- J'ai compris que ma participation est libre et que je pourrai y mettre fin à tout moment, sans que cela n'ait aucune conséquence.

- J'ai bien compris mes droits garantis quant à l'utilisation des données recueillies dans le cadre de cette étude.

- La non-opposition à ma participation ne décharge en rien le coordinateur de l'étude, l'investigateur principal, ni le promoteur (AP-HP), de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.

- Je conserverai un exemplaire original de la présente note d'information et du formulaire de consentement.

Fait à ..... , le ……/……./202… ,

Signature de la personne participant à l'expérimentation, précédée de la mention « Lu et approuvé »

Je soussigné(e)……..(investigateur) certifie avoir informé et recueilli l'accord de non-opposition de la personne susmentionnée selon les dispositions du 3° de l'article L. 1121-1 du code de la santé Publique.

Exemplaire Participant

A version of this form will also be signed for the principal investigator and the study coordinator.