Managing cognitivE decliNe througH theatre therapy, Artificial intelligence and social robots drivEn interventions

D2.4 Ethical standards and data management plan

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0.2	Lars Thomas Boye (TLU)	12-05-2022	TLU data management plan
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0.5	Riitta Hellman (KRD)	24-05-2022	Add IRIS data Management Plan; Final additions and corrections; Review-ready version
0.6	Ionut Anghel (TUC)	24-05-2022	TUC review
0.7	Roberta Bevilaqua (INRCA)	24-05-2022	INRCA review
0.8	Riitta Hellman (KRD)	25-05-2022	Quality check ready version
1.0	Ionut Anghel (TUC)	25-05-2022	Final version

List of acronyms

Acronym	Description
AAL	Ambient Assisted Living
CoC	Code of Conduct
DoW	Description of Work
EC	European Commission
EU	European Union
HUG	Hôpitaux Universitaires de Genève
INRCA	Istituto Nazionale di Riposo e Cura per Anziani
IRIS	Iris Robotics
KPI	Key Performance Indicator
KRD	Karde AS
MCI	Mild Cognitive Impairment
MTR	Mid Term Review
SOME	Social media
TLU	Tellu AS
TUC	Technical University of Cluj-Napoca
WP	Work Package

Content

Executive summary

In this deliverable the engAGE consortium presents the ethical guidelines to be applied in the project. These guidelines cover (a) the national guidelines that the partners are obliged to follow according to national rules and regulations, and (b) the European rules and regulations that follow from the AAL programme and from the European legislation for research ethics, privacy, and data protection.

The ethical principles that were drafted in the project Description of Work (DoW) are collected and systematised in this deliverable.

The data management plans of all partners are also presented. These plans cover both the end user partners' both plans and those of the technical partners; all types of project partners have certain aspects of data management that must be considered along the project's lifetime.

1 Introduction

1.1 Scope and purpose of the deliverable

This deliverable is an output from Work Package (WP) no. 2: **End-user continuous involvement and co-creation** (M1-M26) which has the objectives and partner effort described in Table 1

Table 1: Description of work, objectives

Participant nb.	**5**	**6**	**2**	**1**	**4**	**3**
Participant short name	**HUG**	**INRCA**	**IRIS**	**TUC**	**KRD**	**TLU**
Person-months per participant	**21**	**7**	**7**	**5**	**4**	**4**
Objectives of the WP: focus is the involvement of end-users in all phases of system development and testing including the a) co-creation phase, b) system design, development and fine-tuning and c) provision of information for the development of dissemination and exploitation strategy. Ensure that Ethics by Individual is integrated in all tasks.						

More precisely, this deliverable has been created under Task 2.4, with the description of work as presented in Table 2.

Table 2: Description of work, Task 2.4

Task 2.4	**Ethical standards and data management plan [Leader: KRD, Part: ALL, M1-M26]**
Ethical standards, in terms of fair treatment of participants, respect of human rights, accountability in research, data protection and security, anonymity, etc. will be taken under careful consideration to ensure compliance with European legislation & criteria. The ethical awareness, as well as the project practices, will be based on the AAL Guidelines, GDPR, national legislation, etc. Ethical and legal rules and regulations will be horizontally applied in all work packages, in co-creation, development, and test and evaluation activities of the project, as required by the framework of Ethics by Design, Ethics by Context, and Ethics by Individual. The consortium will apply best practices in data protection and privacy including advanced protection through data security, authentication processes, and encrypted data. Crucial disclaimers will be implemented in the final system operation. The task will lead to the release of D2.4 before users' involvement with the engAGE platform. The ethical management activities will continue until the end of the trial's activities.	

This WP defines the necessary ethical standards as laid out in the project DoW. We also present national ethical requirements and handling of these, as well as ethical approval procedures. For the data management plan, we present those pr. country or pr. partner, as appropriate.

1.2 Goals, challenges, and target groups

The ethical requirements of the engAGE project stem from the fundamental goal definition of the engAGE project: **To combat and slow down cognitive decline progression, to enhance the intrinsic capacity of the users, and supporting the wellbeing of older persons with mild cognitive impairment (MCI).** The engAGE solution provides among several other outputs '**Coaching, cognitive stimulation and social interaction using social robots'**. The interventions are targeting to delay the cognitive decline and improve the ability to carry out daily activities. The interventions will be done by leveraging on the social robot for engaging the older adults (and their caregivers) in theatre and storytelling by sharing narratives about lived events or by dialog and drama role paying. The social robots will be programmed as main intervention devices to provide cognitive stimulation through dialog, drama playing, storytelling, virtual coaching via reminders and step-by-step instructions, and social interaction with friends and family. It will coach and support older adults in self-managing some of the daily living activities by providing reminders and detailed step-by-step instructions, while at the same time it will facilitate social interaction with friends and family to achieve social-emotional goals.

The **intervention aspects** of this provision underline the importance of a good ethical framework for the project's user-centric activities. The activities engage the following main target groups:

- **People with MCI**: theatre and storytelling improve the quality of life and well-being allowing them to preserve their identity, to reduce stresses, memory loss, or communication challenges. The social robot can be a great tool in engaging older adults in this kind of activity. It is always available and able to provide verbal clues or suggestions according to older adult's wishes, needs and memories. Moreover, the social robots may coach the older adults to perform daily activities with greater independence (i.e., coaching stepwise prompting to complete activities in the home) and providing support to caregivers as well.
- **Family caregivers**: caring for people with MCI put a significant burden on family caregivers. Having a social robot acting as a companion of older adults with MCI can reduce some of the anxieties, worries, and stress. The caregivers may personalise the content of robot interventions to the wishes and preferences of the older adults. Together with the older adults they can be involved with the robot in joyful and fun activities like drama playing, storytelling, etc.
- **Healthcare professionals or organisations**: they need to keep track of older adult progress which is a difficult and time-consuming process due to the lack of objective monitoring of cognitive decline and wellbeing. Also, the social robot may ease and facilitate the follow-up on older adults such as reminders and timely supportive cognitive interventions.

2 engAGE main ethical cornerstones

The ethical awareness, as well as the engAGE project practices, will be based on the AAL Guidelines [1]. Also, the project will follow EU and national requirements, recommendations and guidelines in ethics, privacy, and information security.

The use of assistive technology for people with MCI poses several ethical concerns that will be carefully addressed in project implementation ethics by design, context and individual. Individuals and families who live with, or take care of such persons, must make many decisions throughout the disease, including decisions about treatment/therapy/ training, care, and autonomy, participation in society, etc. Similar decisions will also be part of the formal caregiving. Participation in research is yet another issue of ethical concerns. Some are directly related to the characteristics of the technology involved, some to issues of preferences and choices. In all matters concerning the contact with and involvement of older adults and their caregivers, ethics and information security will be strongly in focus.

Ethical issues will be handled by 5 concrete approaches in engAGE:

1. Creating the project's daily ethical guidelines (Code of Conduct) to be followed by all researchers and practitioners participating in the project.
2. Applying for ethical approvals from national ethics boards and committees, per each participating country's research ethical regime, appropriate and necessary for the project's topic.
3. Making all necessary self-declarations and the like, in each participating country vis-a-vis national rules and regulations for data security arrangements and that of handling person (-al)/sensitive data, and privacy.
4. Following relevant EU and national laws, data acts, and directives.
5. Embedding organisational structures and procedures in the project for ethics management.

2.1 Code of Conduct

Daily ethical guidelines (Code of Conduct, CoC) will address the following issues of special relevance:

- *Information*: Any information, requests, and interaction with the (potential) participants will be presented with respect, and in a way that the participant can understand.
- *Willingness to participate*: The engAGE project will bear in any dependencies or other relations between any parties that might influence the end-users feeling of willingness to participate (interviews, field studies, and user tests, etc.).
- *Principle of informed consent to elicit and store data* – freely given, specific, and informed. See also Chapter 2.4.
- *Participants must be allowed to exit* any project stage (such as focus group, experiment, test, or trial) at any time, without any obligation to explain their reasons.
- *Trust and comfort are key issues in home care*. Possible conflicts or stressful relations between primary and secondary end-users (e.g., caregivers requiring monitoring/tracking, and the primary end-user refusing to be monitored) will not offer a fruitful or ethically acceptable point of departure for any test, trial, or pilot.
- *Clarification of who is to be the responsible organisation* and what is the purpose of any data collection, especially who is the controller and processor of any personal data.

The CoC will be created in Task 3.1, Code of conduct, recruitment of end-users and test protocol and will be presented in deliverable D3.1 Code of conduct and evaluation protocol. The project's daily ethical guidelines are to be followed by all researchers and practitioners participating in the project will be defined. The recruitment process will be carried out based on defined eligibility criteria for participants conforming to the ethical procedures defined in Task 2.4.

2.2 Ethical approvals and self-declarations

2.2.1 Italy

In Italy, this project needs to be approved by the Ethical Committee. In order to get the approval, the researchers involved in the project (Dr. Roberta Bevilacqua, Dr. Giulio Amabili, and Dr. Arianna Margaritini) have to submit a detailed protocol where we declare why the research project is carried out, who are the participants, how we recruit them, which data we ask and manage, what questionnaire are asked, what are the safety and security risks for all the people involved in the study, and other things too. Everything should be explained in detail. The Ethical Committee is specific for Science and Health related studies and interventions and meets monthly. Once the approval is achieved, the test activities must follow the guidelines declared in the approved protocol.

2.2.2 Norway

In Norway, this project sorts under the NENT The Norwegian National Committee for Research Ethics in Science and Technology. For the purposes of the engAGE project (development of technology), we do not have to apply for an ethical approval. Karde's WP4 leader, Dr. Riitta Hellman has by The Norwegian Data Protection Authority been registered to be Karde's privacy ombud. She has the competency and capacity to monitor and supervise all ethical aspects connected to the engAGE project's Norwegian part. (Dr. Riitta Hellman's registration letter is provided in Annex 2 – registration letter).

2.2.3 Switzerland

In Switzerland, HUG follows the guidelines presented in Annex 1.

2.3 Informed consent

The consortium will produce a detailed informed consent process that will include information such as:

(a) the purpose of the procedures
(b) the foreseeable risks and discomforts of the end-user
(c) the benefits to the user
(d) the confidentiality of data records
(e) whom to contact for answers, etc.

The informed consent will be signed by each participant of the user involvement or, in the case of cognitive impairment by the person authorised to do so. It will contain a clause informing the user that he or she can quit cooperation at any time without any negative consequences. None of the project activities involving end-user participants constitute clinical research or medical intervention. Nevertheless, *if required*, the appropriate national Ethics Committees will be contacted before starting any activities related to these studies. User tests and pilot trials will reveal the most important parameters concerning dignity. In all cases of fieldwork, the dignity and autonomy of participants will be upheld. By dignity, we mean the personal experience of confidentiality and personal comfort when using or being monitored by ICT. One part of the personal comfort is to use non-intrusive technology solutions, such as small sensors if these are wearable ones, not monitoring the private life through web cameras at all times of day, etc.

2.4 Privacy, integrity and comfort

One very important issue is that the privacy, integrity, and comfort of older adults are respected. Personal data will be collected and processed according to the provisions of the partners' national legislation, fulfilling the General Data Protection Regulation (GDPR) (EU) 2016/679 [2], which is a regulation in EU law on data protection and privacy for all individuals within the EU. The challenge in data privacy is to collect and analyse necessary data while protecting personal and identifiable

information. The consortium will apply best practices in data protection and privacy including providing advanced protection through data security, authentication processes, and encrypted data. Moreover, the data will be fairly and lawfully processed, processed for limited purposes, adequate, relevant, and not excessive, accurate, not kept longer than necessary, processed following the person's rights, secure, and not transferred without adequate protection. When required, approvals for the collection and processing of personal data by the National Data Protection authorities will be acquired. These data will be processed and analysed requiring authorisation by the end-user and/or caregivers.

2.5 Safeguarding data confidentiality

The overriding priority will be to safeguard seniors' confidentiality and to ensure clearly defined processes for different uses of their involvement. engAGE will ensure that no identifiable information is made available without explicit consent. After that the consent has been obtained for the use of personal information, the use of that information, storage, access, and length of storage will form part of the information given to pilot participants before consent. Our approach to confidentiality is to protect the older adults' information by building appropriate access rights, encryption, anonymisation, and provenance techniques into the core models of the engAGE system. During piloting, all personnel involved including system evaluators, service providers, etc., sign a confidentiality agreement to maintain the privacy of involved older employees and their information. Where necessary, their information will be anonymised.

2.6 Ethics procedure for the end-users leaving the pilot

In cases where participants choose to withdraw from or leave during a pilot, the following will apply:

1. Participants collected personal information will be discarded and destroyed.
2. System or devices installed at their working site, if any, will be uninstalled and dismantled and their accommodation will be restored to the same state as before the installations.
3. Participants' who stay until the end of the pilot or end of the project, their personal information will be deleted by the project completion and/or as specified in the consent form. Equally, they may choose to keep system installations or get them dismantled (if any).

The Legal, Ethical, and Security Committee will ensure that all necessary local ethical approvals are obtained. Furthermore, the ethical board will provide advice and observe the ethical practices concerning the relationship between all end-user groups and the project, including caregivers.

In particular, in Task 3.3 Validation of the second prototype in a proof-of-concept study the engAGE second prototype will be evaluated in three different test sites from NO (KARDE), IT (INRCA) and CH (HUG). During the field trials, a proof-of-concept study methodology will be used to explore the impact and validity of the second and complete prototype. *Ethics*, usability, acceptance, and generally, several functional and non-functional system characteristics will be assessed.

2.7 Opt-out, exit strategies and drop-out management

All end-users will be informed about their right to exit the project at any time during the ongoing user evaluation field trials. They can be asked for the reason for exit, but it will be made clear that there is no obligation to answer. End-users will be interviewed about engAGE concerning its effectiveness, perceived usefulness, and user-friendliness but also about what kind of problems might arise, or which factors negatively affect the users' willingness to use the envisioned robot-driven services for cognitive state self-management, stimulation, and social interaction. Partners are aware of the high drop-out rates in research studies and have already provided for proactive (inclusion of a larger cohort of users than sufficient) and reactive strategies (maximisation of recruitment efforts) to mitigate the risks.

Further, people might become dependent on using engAGE technology services and on social robot. Therefore, the consortium will make sure that participants can continue using them after the project ends or the consortium will help the participants to find an alternative solution. The engAGE exit strategy will be adaptively applied when end-users leave the project during implementation or concluding phases to ensure that they do not feel abandoned or lost due to the withdrawal of attention, technology, etc. We will analyse the situation of each end-user involved to detect if some individuals developed a strong dependency, and what possible problems might arise to make the transition as comfortable as possible.

End-users who wish to continue using engAGE services and social after the project ends may be given the option to keep and continue to use them (depending on the cost and financing) or will be guided to an alternative solution for cognitive state self-management. In the first case, they will be also allowed to stay active in a group of other testers leveraging on having engAGE partner organisation acting as launching customer and commercialising the social robot (IRIS). In case of a participant getting a high dependency on the provided services and social robot for self-management and stimulation of cognitive function, a cautionary return to previous habits will be carried out. These kinds of participants will be supported by INRCA and HUG through their services in the re-adapting process. At the end of the project, older adults that require help for re-adapting will be provided with information about alternative help organisations, entities, and web pages providing support for cognitive care self-management. Also, they will be informed when the project results and solutions are available on the market.

2.8 Ethical impact

Ethical impact is another aspect of ethics than those which concern privacy aspects and such. For older adults the engAGE system provides following ethical impacts:

a. Promotion of autonomy, dignity, and self-confidence for a longer time.
b. Social inclusion and empowerment of their networks in a beneficial manner for both parties.
c. Enhancement of their IT literacy and self-confidence: Technology is adapted to them in contrast with them adapting to technology.
d. Better access to cognitive monitoring, healthcare services and outcomes, e) Respect of their preferences, daily life, and decisions.
e. Right to preserve dignity and self-management of health.
f. Better monitoring for remote patients (telehealth services).
g. Right for MCI patients to be included in decision-making processes that interest them, and
h. Right for healthy adults to authorise who views their health data.
i. Promotion of Ethics by Design, gender issues and inclusion.

Also, family members are provided with:

a. Support on how to interact beneficially with their parents and be informed about their cognitive function state, which promotes their sense of security and reassurance.
b. Better healthcare delivery and outcomes for older adults, which means less financial, emotional and physical burden for them. Healthcare professionals and institutions are supported by better management of older adults with MCI (due to holistic monitoring and assessment of cognitive state), which increases their professional confidence, accuracy, revenues, and reputation.

According to our ethical plan, all features provided will ensure the privacy and protection of personal data according to common protocols.

2.9 Ethics management organisation

The **National (Local) Ethics Manager** will monitor project ethics in the countries in which pilots will undergo making sure that the local regulations are respected. In particular, is responsible for:

- Applying for ethical approvals from national ethics boards and committees, according to each participating country's research ethical regime, appropriate and necessary for the project's topic.
- Making all necessary self-declarations and the like, in each participating country vis-a-vis national rules and regulations for data security arrangements and that of handling person (-al)/sensitive data, and privacy.

A **Legal, Ethical and Security Committee** will be comprised of all the National (Local) Ethics Managers and will work with the project Steering Committee to ensure that all EU level ethics are respected and to harmonise potential local (national) ethics-related differences.

The committee, presented in Table 3, will:

1. Define the project's daily ethical guidelines (Code of Conduct) to be followed by all researchers and practitioners participating in the project and
2. Ensure that researchers' interactions with end-users are ethical and best practices ethical management has been applied.

Table 3: Legal, Ethical and Security Committee

Country	Name	Participant
Italy	Anna Rita Bonfigli	INRCA
Norway	Riitta Hellman	KRD
Switzerland	Alexandra Villaverde	HUG

3 European ethical guidelines

3.1 EU and national laws, data acts, and directives

The engAGE project will comply with all National and European regulations and legislations to guarantee adherence to ethical standards and will have a significant impact on users' life ethically and socially. Most important is to fulfil the General Data Protection Regulation (GDPR) (EU) 2016/679 [1], which is a regulation in EU law on data protection and privacy for all individuals within the EU.

3.2 AAL guidelines

For WP2, the DoW requires Ethics by Individual [1] to be implemented in each task. Examples that illustrate these requirements are:

- behaviour and awareness
- aspects that chat can be improved for the end users
- learning how to use the technology
- communication about the (effects of) the new technology
- combatting digital literacy and digital divide
- positive support to the ageing process
- health professionals training to use the new product/service

In the engAGE project, Ethics by Individual will be implemented *in the communication with end users* about the engAGE technology itself. This strategy leans on two main perspectives:

- to ensure that the AAL values (Figure 1) ere embedded in the communication with end-users in all categories
- to ensure that aspects such as those in the bullet list above, are well present when implementing and evaluating ethics in the engAGE project

Implementing and monitoring ethics is a shared task between all WP-leaders, the Legal, Ethical and Security Committee, and the task leader of Task 3.1 Code of conduct, recruitment of end-users and test protocol.

Figure 1: The AAL ethical values. [1]

Then implementation of ethical principles in the WPs of engAGE is fully covered in the in the project. This is illustrated in Table 4.

Table 4: Implementation of the AAL ethical principles in the DoW

Ethics principle	WP1	WP2	WP3	WP4	WP5
Ethics by Design	x				x
Ethics by Context				x	x
Ethics by Individual		x	x		x

3.3 Partner- or country-specific ethical guidelines

3.3.1 HUG (Switzerland)

The Swiss ethical rules and regulations are presented in Annex 1 – national ethical guidelines [4].

3.3.2 INRCA (Italy)

Ethics committees are independent bodies responsible for ensuring the protection of the rights, safety and well-being of trial subjects and for providing public assurance of that protection. Where not already assigned to specific bodies, ethics committees may also perform advisory functions in relation to ethical issues connected with scientific and care activities, with the aim of protecting and promoting the values of the person.

The composition of ethics committees must ensure the qualifications and experience necessary to assess the ethical, scientific, and methodological aspects of the proposed studies. The members of the ethics committees must have documented knowledge and experience in clinical trials of medicinal products and devices medical devices and in other matters within the competence of the Ethics Committee. To this end ethics committees shall comprise at least:

a) three clinicians
b) one territorial general practitioner
c) one paediatrician
d) one biostatistician
e) one pharmacologist
f) one pharmacist from the regional health service
g) in relation to the studies carried out at their premises, the medical director health director or his permanent deputy and, in the case of Institutes of scientific institutions, the scientific director of the institution hosting the trial
h) an expert in legal and insurance matters or a medical doctor legal expert
i) one expert in bioethics
j) one representative from the area of health professions involved in the trial
k) one representative from the voluntary sector or the association of patient protection associations
l) one expert in medical devices
m) in relation to the medical-surgical area under investigation with the medical device under investigation, a clinical engineer or other qualified professional figure
n) in relation to the study of foodstuffs on humans, an expert in nutrition
o) in relation to the study of new technical diagnostic and therapeutic procedures, invasive and semi-invasive, an expert clinical expert in the field
p) in relation to the study of genetics, an expert in genetics

In cases of evaluations relating to areas not covered by its own members, the Ethics Committee shall convene, for specific consultations experts from outside the committee for specific advice.

The investigator, the sponsor or other personnel participating in the trial, shall provide, at the request of the committee information on any aspect of the trial. The investigator, the promoter or other trial personnel shall not participate in the decision-making, opinion and voting of the Ethics Committee ethics committee.

For further details, the law that rules the Ethics Committee is presented in Annex 1 – national ethical guidelines and in [5].

3.3.3 KRD (Norway)

In Norway, the Norwegian National Research Ethics Committees[1] have established 'General guidelines for research ethics. The four main principles are [3]:

Respect. People who participate in research, as informants or otherwise, shall be treated with respect.

Good consequences. Researchers shall seek to ensure that their activities produce good consequences and that any adverse consequences are within the limits of acceptability.

Fairness. All research projects shall be designed and implemented fairly.

Integrity. Researchers shall comply with recognised norms and to behave responsibly, openly and honestly towards their colleagues and the public.

The whole document (a "poster") is shown in Annex 1 – national ethical guidelines.

These guidelines define the research ethical guidelines for the Norwegian partners, in addition to the CoC of the engAGE project.

[1] NEM The Norwegian National Committee for Medical and Health Research Ethics
NENT The Norwegian National Committee for Research Ethics in Science and Technology
NESH The Norwegian National Committee for Evaluation of Research on Human Remains
GRANSKINGSUTVALGET The Norwegian National Commission for the Investigation of Research Misconduct

4 Data management plan

The engAGE project organises its data management plan by project participant or by country. The plans are shown in Annex 3 – data management plans.

The end user organisations data management plans focus on the ethical management of user-centric and co-creation activities.

The technical partners' data management plans focus on how monitored data is stored, how data security is achieved, etc.

External systems and services that will be used in the research and development work of the project, such as questionnaire applications, will be subject to special procedures, including privacy information to informants, anonymised responses as well as denial of access to other informants' responses.

5 References

[1] C. Dantas et. al.: AAL Guidelines for Ethics, Data Privacy and Security. http://www.aal-europe.eu/wp-content/uploads/2020/08/AAL-guidelines-for-ethics-final-V2.pdf

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

[3] Norwegian National Research Ethics Committees: General guidelines for research ethics. https://www.forskningsetikk.no/en/guidelines/general-guidelines/

[4] https://swissethics.ch/en/

[5] https://www.gazzettaufficiale.it/eli/id/2013/04/24/13A03474/sg

Annex 1 – national ethical guidelines

Italy

Regulation of organization and functioning of the
National Coordination Center of Territorial Ethics Committees for Clinical Trials on Medicinal Products for Human Use and Medical Devices

Art.1

(Object)

1. These Regulations govern the procedures for the organization and functioning of the National Coordination Center of Territorial Ethics Committees for Clinical Trials on Medicinal Products for Human Use and Medical Devices (hereinafter referred to as the "Coordination Center"), established by Decree of the Minister of Health of April 19, 2018.

Article 2

(Activity and mode of operation)

1. The Coordination Center performs the functions identified in Article 3 of the aforementioned Ministerial Decree of April 19, 2018.
2. The Coordination Center meets as a rule once a month, as well as in all cases in which the President considers it necessary, or if it is requested by at least one third of the members. The meetings are convened by the Secretariat referred to in Article 4.
3. Meetings of the Coordination Center shall be valid when a majority of the members are present.
4. The decisions of the Coordination Center are adopted by a majority of those present and, in cases of parity, the President has the casting vote. For issues of particular importance, identified by the Coordination Center, such as the adoption of the single model contract or the proposal for the abolition of a Territorial Ethics Committee, decisions are taken on the basis of a qualified majority of two thirds of the members.
5. The components referred to in Article 1, paragraph 1, of the aforementioned Ministerial Decree of April 19, 2018, as well as the participants by right referred to in Article 1, paragraphs 2 and 4, of the same Decree, participate in the work of the Coordination Center.
6. The participants by right referred to in Article 1, paragraphs 2 and 4, of the aforementioned Ministerial Decree of April 19, 2018 do not exercise ii right to vote, but may express ii opinion on the issues being dealt with by the Coordination Center and be heard by the members of the same Center.
7. Both components and participants:

   a) may submit to the President of the Coordination Center reasoned proposals for integration or modification of the agenda, requesting the discussion of specific issues;

   b) may formulate to the President of the Coordination Center a motivated request for an extraordinary convocation of the same.

8. At the request of the President or at least one of the members, any external experts with expertise in the specific subject matter may be heard at meetings of the Coordination Center.
9. Also for the purposes of rationalization of operating expenses, and guaranteed participation in distance to the sessions, through telematic modalities, both for the components and for the participants by right.
10. If, as a result of resignation or for any other reason, the duties of one or more of the following persons are terminated

more components, up to a maximum of two, pending the appointment of substitutes and in order to ensure continuity of operations aimed at the performance of the functions assigned, the meetings

are valid if the majority of the members in office are present.

Article 3

(Obligations of the Components)

1. The members of the Coordination Center carry out their activities with transparency, objectivity, responsibility and independence.
2. The members are required to respect the obligation of confidentiality, not to use for private purposes the elements acquired or of which they have become aware in the performance of their duties and not to take initiatives likely to create prejudice to the institutional activity carried out and the objectives pursued.
3. The members are required to declare, with periodic annual self-certification, that they are free from any undue influence and that they have no financial or personal interests that could potentially affect their impartiality. Should they find themselves in a situation of conflict of interest during the course of their activity, they are obliged to promptly inform the Secretariat and to refrain from taking part in the discussion and deliberation on matters for which said conflict exists. To this end, the members are required to sign, before the holding of each session, a declaration of incompatibility, to be delivered to the Secretariat.
4. The obligations referred to in paragraphs 1, 2 and 3 are also extended to the participants by right in the work of the Coordination Centre, as well as to those invited to participate in accordance with Article 2, paragraph 7.

Article 4

(Coordination Center Secretariat)

1. The Secretariat of the Coordination Center is located at the Pre-authorization Area of the Italian Drug Agency. Communications addressed to the Coordination Center are,

therefore, transmitted to the e-mail address published in the appropriate section of the Agenzia Italiana del Farmaco website.
2. The Secretariat, on indication of the President, convenes the meetings of the Coordination Center; it takes care of the minutes and the recording of the meetings. The Secretariat, always on indication of the President, organizes the meetings of the Center and assists the components and the participants by right in the performance of their functions, also providing a technical and operational support.
3. The Secretariat receives and acquires for the records of the Italian Medicines Agency, the declarations attesting the absence of conflicts of interest, made annually by the members of the Coordination Centre, as provided for in Article 2 of the Ministerial Decree of April 19, 2010.

2018, and acknowledges in the minutes of the meetings any conflicts of interest declared by the members in relation to specific topics discussed at the meeting.

Articl e 5

(Agenda, convocations and minutes)

1. The meetings of the Coordination Center are convened by the President through the Secretariat referred to in Article 4.
2. Notices of meetings, addressed to members and participants by right, are sent to by the Secretariat at least seven days prior to the date of the meeting via email.
3. The agenda of the meetings is set by the President and sent to the members and participants by right at the same time as the convocation of right at least seven days before of the date of the meeting. The same one can be modified or integrated on demand, to submit to the President.
4. Each meeting of the Coordination Center shall be minuted and recorded. The recordings of the meeting are confidential and are not accessible to third parties, except as provided for in the legislation on access to documents.
5. The minutes will be sent by the Secretariat referred to in Article 4 to the members of the Coordination Centre and the participants by right, within five working days of the meeting. session. It is approved in the meeting following that which is the subject of the minutes or by telematic means.

Articl e 6

(Development of the activities of the Center)

1. For the purposes of carrying out the functions assigned to the Coordination Center of Article 3, paragraph 2, of the Ministerial Decree of April 19, 2018, certain operational procedures are dictated below.
2. In order to monitor the activities carried out by the territorial ethical committees and to report any cases of inertia and failure to comply with the terms of the law, the Secretariat makes available to the Coordination Center the data extracted from the National Observatory for Clinical Trials. Where necessary, for the purposes of data processing, reference can be made to the EudraCT database or to AIFA's internal databases, or data available to the Ministry of Health can be requested. These operating procedures will be updated following the implementation of the European portal for clinical trials, according to the available functionalities.
3. The Coordination Center shall notify the territorial ethics committees of non-compliance with the prescribed deadlines for the evaluation of clinical trials.
4. The Coordination Center shall also forward to the Minister of Health any proposal for the suppression of a territorial ethical committee in case of repeated inertia or failure to comply with the law. To this end, the Coordination Center defines, with a separate act, the criteria and procedures for evaluating cases of inertia and failure to comply with the deadlines of the law by the territorial ethics committees, in order to propose their suppression.
5. The Coordination Center shall also define the minimum content of the contract relating to the clinical trial, to be approved by a qualified majority of two thirds of those present.

6. Requests for support and advice on the ethical evaluation of clinical trials, formulated by the territorial ethics committees to the Coordination Center, are addressed to the Secretariat mentioned in article 4, which verifies the completeness and relevance of the documentation received, to be submitted to the same Coordination Center in the first useful meeting. In case of urgent questions, related to clinical trials for which the timing does not allow to wait for the first useful regular meeting, the President, through the Secretariat, calls for an urgent convocation also by telematic means.
7. The Coordination Center, at the request of the Italian Medicines Agency, may express an opinion on clinical trials that require revision following the reporting of adverse events. In the case of multinational trials, the opinion must be expressed within the timeframe provided by the respective procedure at European level. To this end, the Clinical Trials Office sends the relevant documentation to the Secretariat, which will include the issue on the agenda of the first useful meeting.

Article 7

(Transparency and publicity of acts)

1. All documentation of the Coordination Center, including recordings of individual meetings, is confidential and not accessible to third parties, subject to the provisions of the regulations on access to records.

Articl e 8

(Fees)

1. The members of the Coordination Center are not paid compensation or emoluments, however denominated, other than those indicated in Article 4 of the aforementioned Ministerial Decree of April 19, 2018 .

Rome, li 14 febbraio 2018

Maria Luisa Moro

Norway

The Norwegian National RESEARCH ETHICS COMMITTEES

General guidelines for research ethics

Research is of great importance – to individuals, to society and to global development. Research also exercises considerable power at all these levels. For both these reasons, it is essential that research is undertaken in ways that are ethically sound.

PRINCIPLES

- **Respect.** People who participate in research, as informants or otherwise, shall be treated with respect.
- **Good consequences.** Researchers shall seek to ensure that their activities produce good consequences and that any adverse consequences are within the limits of acceptability.
- **Fairness.** All research projects shall be designed and implemented fairly.
- **Integrity.** Researchers shall comply with recognized norms and to behave responsibly, openly and honestly towards their colleagues and the public.

1 **Quest for truth.** Research activity is a quest for new knowledge, with critical and systematic verification and peer review. Honesty, openness, systematicness and documentation are fundamental preconditions for achieving this goal.

2 **Academic freedom.** Research institutions shall assist in ensuring the researchers' freedom in their choice of topic and methodology, implementation of research and publication of results. In commissioned research, the commissioning agency has the right to define the topic, research questions and scope of the research assignment in cooperation with the person or institution undertaking the assignment. The commissioning agency should not seek to unduly influence choice of methodology, implementation or publication.

3 **Quality.** Research should be of high academic quality. The researcher and institution are required to possess the necessary competence, design relevant research questions, undertake suitable choices of methodology and ensure sound and appropriate project implementation in terms of data collection, data processing and safekeeping/storage of the material.

4 **Voluntary informed consent.** Consent is the main rule in research on individuals or on information and material that can be linked to individuals. This consent should be informed, explicit, voluntary and documentable. Consent presupposes the capacity to give such consent. To ensure real voluntariness, vigilance must be exercised in cases where the participant is in a dependency relationship to the researcher or in a situation of restricted freedom.

5 **Confidentiality.** As a general principle, those who are made the subjects of research are entitled to have their personal information treated confidentially. The researcher must prevent any use and communication of information that might inflict damage on individuals who are the subjects of research. Irrespective of the duty of confidentiality, researchers have a legal obligation to avoid punishable offences. The researcher must decide when and in what way the participant should be informed about limitations of the duty of confidentiality.

6 **Impartiality.** Impartiality means avoidance of confusing roles and relationships in a way that may give rise to reasonable doubt concerning conflicts of interest. Openness regarding relevant roles and relationships that the researcher is involved in must be maintained in relation to colleagues, research participants, sources of finance and other relevant parties.

7 **Integrity.** The researcher is responsible for the trustworthiness of his or her own research. Fabrication, falsification, plagiarism and similar serious violations of good academic practice are incommensurate with such trustworthiness.

8 **Good reference practice.** Researchers must adhere to good reference practices, which fulfil requirements for verifiability and form the basis for further research.

9 **Collegiality.** Researchers must show each other respect. They must agree on and comply with good practices for data ownership and sharing, authorship, publication, peer review and cooperation in general.

10 **Institutional responsibility.** The responsibility for ethical conduct rests not only with the individual researcher, but also with the research institution. The institution is responsible for ensuring compliance with good academic practice and for establishing mechanisms that can address cases of suspected violations of ethical research norms.

11 **Availability of results.** As a main rule, research results should be made available. Openness regarding research findings is essential for ensuring verifiability, for returning some benefit to the research participants and society in general, and for ensuring a dialogue with the public. Such communication is also a function of democracy.

12 **Social responsibility.** Researchers have an independent responsibility to ensure that their research will be of benefit to research participants, relevant groups or society in general, and for preventing it from causing harm. Research decisions must take into account any knowledge that the development of a research area may entail ethically unacceptable consequences for individuals, animals, society or the environment. It is absolutely essential that when participating in public debate, the researcher clearly distinguishes between professional comments made in his or her capacity as an expert on the one hand and statements of personal opinion on the other, and refrains from abusing his or her authority.

13 **Global responsibility.** Research institutions and researchers have a responsibility to communicate relevant knowledge to regions that are otherwise excluded for reasons of economic disadvantage. Research should help counteract global injustice and preserve biological diversity.

14 **Laws and regulations.** In the field of research, there are national laws and regulations as well as applicable international conventions and agreements, and researchers and research institutions must abide by these.

NEM • The Norwegian National Committee for Medical and Health Research Ethics **NENT** • The Norwegian National Committee for Research Ethics in Science and Technology
NESH • The Norwegian National Committee for Evaluation of Research on Human Remains **GRANSKINGSUTVALGET** • The Norwegian National Commission for the Investigation of Research Misconduct

Switzerland

swissethics

Schweizerische Vereinigung der Forschungsethikkommissionen
Association suisse des Commissions d'éthique de la recherche
Associazione svizzera delle Commissioni etiche della ricerca
Swiss Association of Research Ethics Committees

BASIC RESEARCH: Guidance for researchers

This guiding document is intended for researchers who conduct basic research projects with persons according to chapter 2 HRO and for further use projects of human biological material with or without associated health-related personal data according to chapter 3 HRO.

The guiding document addresses the most common omissions made during the planning and writing of project research plans (study protocols) for basic research projects and addresses some of the questions raised by the researchers on the submission of those projects to the ethics committees.

What constitutes exactly «basic 'medico scientific' research» and does it fall within the scope of The Federal Act on Research involving Human Beings (HRA, HFG, LRH, LRUm)?

A broad general definition of **Basic Research** defines it as a synonym for fundamental research, which is the study of life processes. It includes for example cell studies, biochemical, genetic and physiological investigations, and studies on the properties of drugs and materials in contact with human biological material, i.e. cells or tissues.
Basic research also includes the development and improvement of analytical procedures such as analytical determination of enzymes, markers or genes
The development of biometric procedures such as statistical test procedures, modeling and statistical evaluation strategies also belongs here[1].

The **Federal Act on Research involving Human Beings** (Human Research Act, HRA) applies to research concerning **human diseases** and concerning the **structure and function** of the human body (HRA Art. 2 Abs 1). It does apply to uncoded or coded but not to anonymized[2] biological material and anonymously collected nor to anonymized health-related personal data[3] (HRA Art 2 Abs 2).

Basic research projects as mentioned above may fall within one of several different study categories subjected to prior ethics committee approval. When planning a basic research project, it is thus worth considering if the project can alternatively be conducted with anonymized human biological material and anonymized or anonymously collected health-related personal data, instead of using uncoded or coded[4] biological material and data. It is emphasized here that the anonymization of biological material and associated health-related personal data might not always be possible, practicable or even desirable. A research project conducted with anonymous biological material and associated anonymous health-related personal data does not fall within the scope of the HRA and thus it does not require an ethics committee approval.

[1] Modified from: Dtsch Arztebl Int. B. Röhrig et al. 2009 Apr; 106(15): 262–268.
[2] Anonymized biological material and anonymized health-related data means biological material and health-related data which cannot (without disproportionate effort) be traced to a specific person.
[3] Health-related personal data means information concerning the health or disease of a specific or identifiable person, including genetic data.
[4] Coded biological material and coded health-related personal data means biological material and data linked to a specific person via a code.

The researchers have to describe the procedure of anonymization in the project research plan and must inform the donors on the proposed anonymization of their biological material and related personal data for research purposes, especially on the consequences of anonymization with regard to results concerning their health, and on their right to dissent (HRO Art. 30).

In case of doubt on whether the research project requires ethics committee approval, the researchers should submit a clarification of responsibility[5] through the web-portal BASEC to the ethics committee for clarification, before starting the project. The procedure is given here.

What are the most common omissions made during the submission of a project of basic research to the ethics committee?

Quick links:

1. Missing information on the origin and storage of the biological material (e.g. missing biobank regulation, material transfer agreement)

The origin of the biological material used for the research must be given in detail in the research plan. If the biological material is obtained from different sources, all sources must be listed.
The material transfer agreement (MTA)[6] must be submitted to the ethics committee through the web-portal BASEC, as a standalone document. The MTA should not be integrated in or annexed to the project research plan.

Additionally, the researchers must indicate if the biological material and, if applicable, the associated health-related personal data will be received and used in uncoded or coded form. It also should be explained how the donors will consent or have consented to the use of their biological material for research (general consent, project specific consent, no consent for all – some of the samples[7]).

[5] The clarification of responsibility is called in German "Zuständigkeitsabklärung", in French "Clarification des compétences", and in Italian "Esame della competenza".
[6] The MTA is a legally binding agreement that governs the transfer of biological material and data between two parties, when the recipient intends to use them for research purpose. It defines the rights and obligations of the provider and recipient with respect to the use of the material and data and other related issues, such as confidentiality or intellectual property rights. A template to write the MTA can be downloaded from the webpage of the Swiss Biobanking Platform (swissbiobanking.ch).
[7] If no consent for all – some of the samples/data exist, HRA Art. 34 might apply.

If the biological material is obtained from a biobank, the biobank regulation[8] must be submitted to the ethics committee through the web-portal BASEC, as a standalone document. The biobank regulation should not be integrated in or annexed to the project research plan.

For biological material and/or data imported from abroad, proof of legality (e.g. an ethics committee positive decision from country of origin of the biological material, material transfer agreement or similar verification document) is needed.

The sample size (amount of blood or other biological material) used for the research project should always be given (see also below point 5. 'Missing / incomplete statistical analysis plan').

2. Use of «research-products»[9], including commercially available human cell-lines and use of non-commercially available human cell-lines

A basic research project with cell lines falls within the scope of the HRA if it is a method-driven search for generalizable knowledge (Art. 3, a, HRA) and if the biologic material used in the research project is coded (Art. 3, h, HRA) or uncoded (i.e. not anonymized, Art. 3, i, HRA).

Generally, research projects that use exclusively commercially available cell-lines (e.g. HeLa, HEK-293, Jurkat, etc.) or publicly available cell-lines do not fall within the scope of the HRA and as such do not require ethics committee approval. These cell-lines are so called «research-products» that have been produced or developed on the basis of human cell material. The processing steps have created a «research-product» from the donor's isolated biological material, which is no longer considered a «part of the human body»[10].

Human biological material becomes a «research-product» if it was substantially processed.[11]
Substantially processed means it underwent at least one of the following processing steps:

a) the multiplication of cells via cell culture;
b) the genetic modification of cells, or
c) the differentiation or activation of cells.

Thus, by analogy, human biological material is also considered a «research-product» if the substantial processing took place in animals (e.g. xenograft animal models, human cell-line derived xenograft (CDX), or patient derived xenograft (PDX)).

When should the researchers obtain a written informed consent, i.e. a study specific consent or a general consent for the further use of the donor's biological material, and when is an

[8] The biobank regulation is a document that defines the biobank purpose, activities, organization and reflects its daily practices. More detailed information on biobanks/biobank regulations can be found on the webpage of the Swiss Biobanking Platform (swissbiobanking.ch).
[9] This section 2 does not apply to products in scope of the Medical Devices Ordinance (MepV, SR 812.213) of 1 July 2020 and the Clinical Trials with Medical Devices Ordinance (KlinV-Mep, SR 810.306) of 1 July 2020.
[10] Dispatch on the Federal Human Research Act, of 21 October 2009, Chapter 2.1.2.6 Prohibition of commercialisation (Art. 9) (in German, in French, in Italian)
[11] In analogy to the regulations on definition of transplantation products (which are not considered part of the human body as well) described in the Transplantation Act of 8 October 2004 (SR 810.21) and Transplantation Ordinances of 16 March 2007 (SR 810.211), which are referenced in in chapter 2.1.2.6 of the Dispatch on the Federal Human Research Act of 21 October 2009.

informed consent not required? Here we distinguish between research projects with human biological materials that fall within the scope of the HRA and projects that are not in scope.

1. **Research projects that fall within the scope of the HRA.** The researcher must obtain the written informed consent of the donor before its biological material can be used in the research project. The origin of the biological material and confirmation that the informed consent of the donor was properly obtained must be submitted to the ethics committee with the application. The research project cannot begin previous approval by the ethics committee.

2. **Research projects that do not fall within the scope of the HRA.** There is no legal obligation for the researcher to obtain the donor's written informed consent for the use of the donor's biological material in the project. However, the trust of the participants in research projects and in the biomedical research in general, which is built on transparency and fair communication, is fundamental for the research involving human beings. It is therefore for ethical reasons that swissethics recommends that the researchers undertake the necessary efforts to obtain the written consent of the donors whenever possible.

3. Use of biological material (cells) from healthy volunteer for testing, controls, etc.

If biological material (cells) from healthy volunteers are used for example as negative control in an experiment, as feeder cells, for the establishment of cell-staining, for tests-runs made before an important experiment, etc., in the context of a research project to study human diseases or the structure and function of the human body (again method-driven search for generalizable knowledge) then the research project falls within the scope of the HRA and requires ethics committee approval.

If the biological material (cells) is not used in the context of a research project to study human disease or the structure and function of the human body, then its use does not fall within the scope of the HRA. However, a general consent or a specific written informed consent must be obtained from the volunteers (donors).

In case of doubt, before starting the research project, the researchers should submit a clarification of responsibility through the web-portal BASEC to the ethics committee to clarify whether the research project falls within the scope of the HRA. The procedure is given here.

4. Undefined / vague projects objectives and endpoints

Although it may not always be possible to give clear cut endpoints when conducting basic research projects, well-thought-out research objective(s) should be provided. The researchers should provide with the initial submission the raw road map, supported with hypotheses, pre-study observations, etc., on how the research objective(s) have been set.

The researchers are invited to discuss beforehand with the ethics committee if changes to the project objective(s) should be submitted to the ethics committee as a substantial amendment to the project research plan or as a standalone new research project (for more details, see below the chapter 6. 'Changes to the project research plan during the course of the project (amendments)).

5. Missing / incomplete statistical analysis plan

For some basic research projects, it may not be possible to write a detailed statistical plan, as instructed in the swissethics template for project research plan for HRO Chapter 2 research projects, i.e. with detailed statistical methods, level of significance, power, etc. Nonetheless, if different statistical methods (e.g. descriptive statistic) rather than hypothesis testing are used, those should be described in detail.

It is advised to consider the statistical aspects of the project (type of statistical analysis, sample size, etc.) very early in the stage of project planning/ research plan writing.
A justification of the sample size (expected total number of samples/quantities used, expected samples/quantity used per single donor, etc.) should always be given.

If the research does not foresee any statistical analysis at all, this must be justified in the study research plan.

6. Changes to the project research plan during the course of the project (amendments)

A guidance document for researcher on "notification of substantial amendments and other changes to the ethics committee" is published on the swissethics webpage (template/checklists/notifications). The document also includes a comprehensive list of changes and their classification in substantial and non-substantial amendments. For example:
Addition of research sites, change of the project leader, or changes to the patients' group without simultaneously changing the project's objectives, are substantial changes and must be submitted to the ethics committee and approval obtained before the changes are implemented. Changes to the research centre's SOPs, working instructions, etc. are not substantial changes and can be implemented immediately.

It should be noted here, that changes to the patients group combined with a change of the project's objectives must be submitted as a new research project. In some cases, the submission of a change as new standalone study protocol, might even be advantageous for the conduct of the project itself[12].

The researchers are invited to discuss beforehand with the ethics committee on how to submit changes that are not listed on the guidance document, if it is not immediately clear to what extend the changes listed on the guidance document also concern the projects of basic research, or if the submission of a new research project would be advantageous instead.

Depending on the classification, the ethics committee might also decide that the substantial change to the project research plan is submitted as a new standalone study protocol.

7. Missing information on the handling of incidental findings

The handling of incidental findings should not only be described in the patient information /informed consent form, but also in the project research plan.
To properly address this point in the project research plan, the researchers are advised to consult the document «guideline for handling incidental findings in medical search»[13] and the

[12] For example, fewer regulatory requirements if the study population is changed from minors to adults, while other changes to the study protocol might significantly simplify the statistical analyses, etc.
[13] swissethics, the document is available in German, French, Italian.

document «Ethical Framework for Responsible Data Processing in Personalized Health Research»[14], for guidance.
Only validated clinically actionable findings should be communicated to research participants through competent healthcare professionals, as agreed at the consent. This means that if a research participant does not want to be informed, her/his choice must be respected.

8. Incomplete information to the donors on genetic investigation

If genetic analysis is done in clinical routine, the Federal Act on Human Genetic Testing (HGTA[15]) applies, while genetic investigations (germline and non-germline) fall within the scope of the HRA (Art. 3, Abs c).
In case of genetic investigation, the donors must be informed that their genetic information (DNA sequences, etc.) may be deposited in national or international databases (e.g. SIB, NIH SNPdb), if this is the case. Some databases explicitly require confirmation and proof that the donors have given their written informed consent for the genetic investigations and for the storage of the genetic information (DNA sequences, sequence variants, genes, etc.). If cloud computing of storage is used for storage, this should be mentioned in the research study plan and the informed consent form.

Before providing the data, the researchers should check that the databases are compliant to the European General Data Protection Regulation (GDPR) or to the Swiss Federal Act on Data Protection (FADP[16]).

9. Missing or unprecise information on what happen to the biological material /health-related personal data at the end of the project

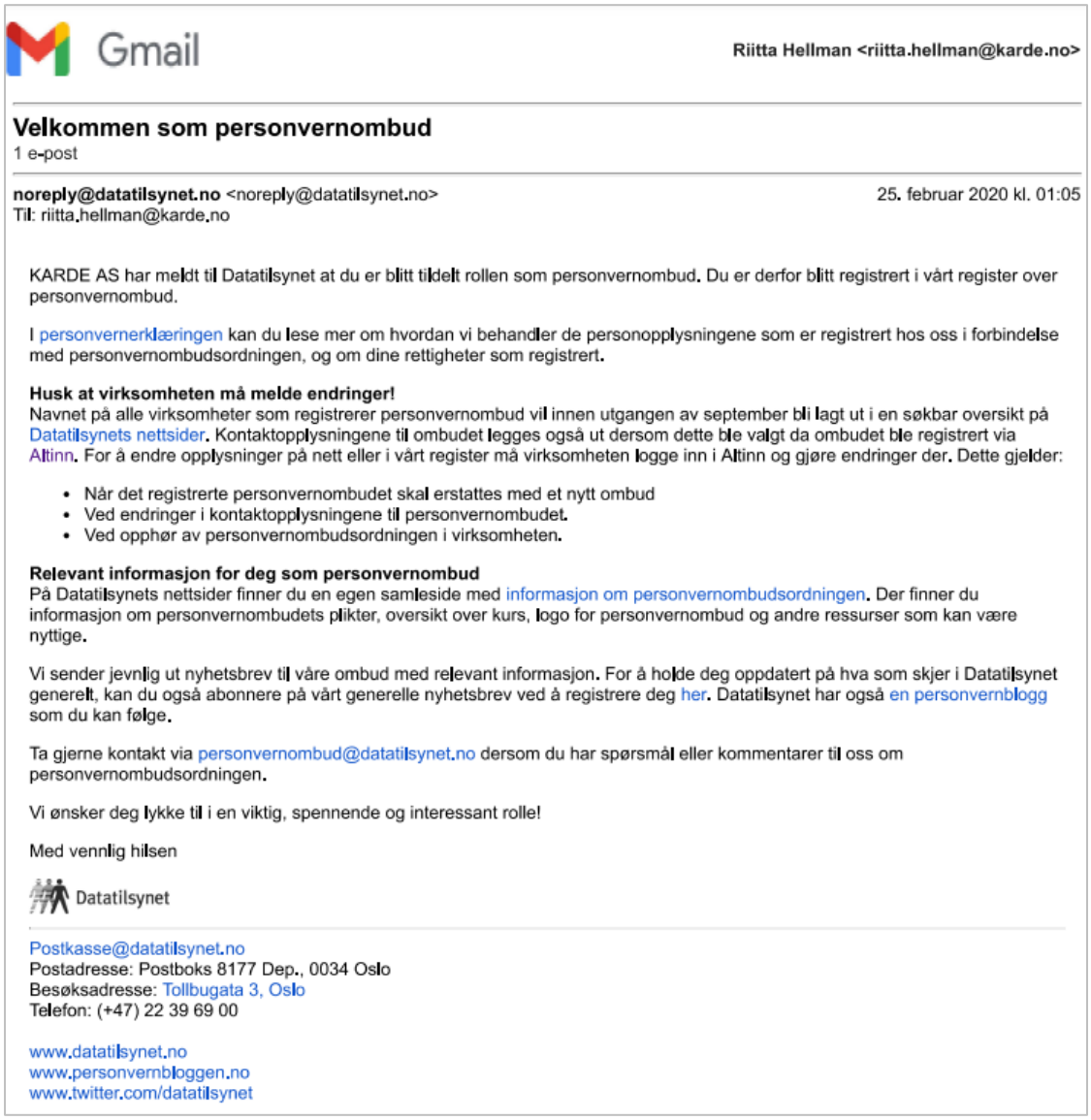
An expected end date of the project must always be submitted to the ethics committee with the initial submission. The researchers should describe in the project research plan what happens to the biological materials and health-related data at project end: e.g. "After analysis, the biological material will be destroyed at the research center, as per internal SOPs, and the coded data stored for *y* years at the hospital (address *x*)."

If the biological material is not immediately destroyed after use, the place and period of storage must be indicated in the project research plan: e.g. "After information to the participants/donors, as per HRO art. 30, the biological samples and the associated health-related personal data are anonymized after evaluation, i.e. the coding-key is destroyed, and stored at the research center (address *x*) for *y* years." or: e.g. "The remains of the unused samples are sent back to the hospital biobank (address *x*) and stored there for *y* years."

If it is planned to reuse the biological material and associated personal data for future, not yet defined, research projects in Switzerland or send them abroad, the donors must be informed accordingly and give their written consent (a template for writing an informed consent is available on the swissethics webpage).

[14] ELSI Advisory Group, published by SPHN in English.
[15] Bundesgesetz über genetische Untersuchungen beim Menschen (GUMG); Loi fédérale sur l'analyse génétique humaine (LAGH); Legge federale sugli esami genetici sull'essere umano (LEGU)
[16] Bundesgesetz über den Datenschutz (DSG); Loi fédérale sur la protection des données (LPD); Legge federale sulla protezione dei dati (LPD)

Annex 2 – registration letter



Gmail

Riitta Hellman <riitta.hellman@karde.no>

Velkommen som personvernombud

1 e-post

noreply@datatilsynet.no <noreply@datatilsynet.no> 25. februar 2020 kl. 01:05
Til: riitta.hellman@karde.no

KARDE AS har meldt til Datatilsynet at du er blitt tildelt rollen som personvernombud. Du er derfor blitt registrert i vårt register over personvernombud.

I personvernerklæringen kan du lese mer om hvordan vi behandler de personopplysningene som er registrert hos oss i forbindelse med personvernombudsordningen, og om dine rettigheter som registrert.

Husk at virksomheten må melde endringer!
Navnet på alle virksomheter som registrerer personvernombud vil innen utgangen av september bli lagt ut i en søkbar oversikt på Datatilsynets nettsider. Kontaktopplysningene til ombudet legges også ut dersom dette ble valgt da ombudet ble registrert via Altinn. For å endre opplysninger på nett eller i vårt register må virksomheten logge inn i Altinn og gjøre endringer der. Dette gjelder:

- Når det registrerte personvernombudet skal erstattes med et nytt ombud
- Ved endringer i kontaktopplysningene til personvernombudet.
- Ved opphør av personvernombudsordningen i virksomheten.

Relevant informasjon for deg som personvernombud
På Datatilsynets nettsider finner du en egen samleside med informasjon om personvernombudsordningen. Der finner du informasjon om personvernombudets plikter, oversikt over kurs, logo for personvernombud og andre ressurser som kan være nyttige.

Vi sender jevnlig ut nyhetsbrev til våre ombud med relevant informasjon. For å holde deg oppdatert på hva som skjer i Datatilsynet generelt, kan du også abonnere på vårt generelle nyhetsbrev ved å registrere deg her. Datatilsynet har også en personvernblogg som du kan følge.

Ta gjerne kontakt via personvernombud@datatilsynet.no dersom du har spørsmål eller kommentarer til oss om personvernombudsordningen.

Vi ønsker deg lykke til i en viktig, spennende og interessant rolle!

Med vennlig hilsen

Datatilsynet

Postkasse@datatilsynet.no
Postadresse: Postboks 8177 Dep., 0034 Oslo
Besøksadresse: Tollbugata 3, Oslo
Telefon: (+47) 22 39 69 00

www.datatilsynet.no
www.personvernbloggen.no
www.twitter.com/datatilsynet

Annex 3 – data management plans

HUG

Data management plan (HUG- CH)

University Hospitals of Geneva (HUG) will help regarding end-users involvment in the project by providing templates, protocols and deliverables. The aim of HUG is to help involving end-users around three European sites during all important phases of the project in order to co-create the component of the digital solution.

Data collected through co-creation and evaluation phases with end-users will all be collected anonymously and delivered to technical partners of the University of Cluj-Napoca (coordinator, Romania) and to INRCA (responsible for end-users studies in Italy) and Karde AS (responsible for end-users studies in Norway). The aim of the data sharing is to develop an improved technology solution which will grasps the end-users situations and needs by helping them to stabilize or empower their cognitive faculties.

To ensure the development of a digital solution, an end-user centered approach will be adopted during all the stages of maturity of the engAGE software/hardware. No personal information on diagnoses or medication concerning Mild Cognitive Impairment (MCI) or dementia will be asked or stored.

To involve end-users we will contact associations or HUG patients by clearly informing them on the stages of the research, the aim, the purpose targeted in order for them to give a fully consent. The study has no risks identified, end-users will be shielded from any intrusive or unnecessary questions as far as the projects (one and only) technology goal is concerned.

HUG will be the responsible partner for collecting and creating the aggregated Swiss data for the consortium. Following aspects cover our data management approach:

- All individual data sheets of the end-user participating in the tests and trials will be coded and not include any information allowing the participant's identification.
- HUG will not keep these data over time neither electronic nor on paper
- HUG data sheets with interview data will be destroyed at the end of the project

Each partner will follow all necessary rules and guidelines for data management concerning the project's data.

Contact person for data management in HUG is Pr. Christian Lovis and is supported by Alexandra Villaverde Naveira.

INRCA

Data management plan (IRCCS INRCA - IT)

The Italian National Institute for Health and Sciences on Ageing (IRCCS INRCA) will help regarding end-users involvment. The aim of INRCA is involving Italian end-users during all important phases of the project in order to get insights about end users' perspective to be shared with all the project partners. Furthermore, INRCA will lead the evaluation part of the research project in order to assess the impact of engAGE on end users' life.

Data collected through co-creation and evaluation phases with end-users will all be collected anonymously and shared with technical partners of the University of Cluj-Napoca (coordinator, Romania) and to HUG (responsible for end-users studies in Switzerland) and Karde AS (responsible for end-users studies in Norway). The aim of the data sharing is to develop an improved technology solution which will grasp the end-users' conditions and needs by helping them to stabilize or empower their cognitive abilities.

To involve end-users we will contact associations or INRCA patients by clearly informing them on the stages of the research, the aim, the purpose targeted in order for them to give a fully consent. The study has no risks identified, end-users will be shielded from any intrusive or unnecessary questions as far as the projects (one and only) technology goal is concerned.

INRCA will be the responsible partner for collecting and creating the aggregated Italian data for the consortium. Following aspects cover our data management approach:

As an Italian institution, INRCA applies to the European General Data Protection Regulation (GDPR EU 2016/679). Due to that:

- All individual data sheets of the end-user participating in the tests and trials will be coded and not include any information allowing the participant's identification (anonymization of data);
- INRCA will not keep these data over time neither electronic nor on paper;
- INRCA data sheets with interview data will be destroyed when no needed anymore (end of project or publications);

Contact person for data management at IRCCS INRCA is Dr. Roberta Bevilacqua.

IRIS

Data management plan for IRIS Robotics (IRIS)

During the research and development phases of the project lifetime each technical partner will provide its own infrastructure for hosting the developed components, processing, and storing personal data collected through the engage platform in Romania and Norway into Iris, TUC, Tellu and KARDE premises. After the end of the project when exploitation, IP and business plans will be established it will be decided how hosting and data storage will be managed under a live production environment. Thus, a critical area of security is the servers (cloud or on-premises) where the solutions will be deployed, or on which data will be stored. These need to be provided with physical and logical protection.

All the personalized interaction scenarios which will be created during the project will be implemented according to the data and analysis provided by the end-user partners.

Data and content available on robot will define the storytelling scenario with the patience and are stored on cloud. Thus, the available content of the robot will be created based on the feedback of patients collected by the end-user partners and we will not collect any personal data from the end-user.

Regarding the installation and upgrades of Android app which will be created, the app will be downloaded by each end-user partner directly on the robot and for new updates and improvements we will send APK through Command Center to the end-user.

Among the IT security techniques available, data pseudonymisation or anonymization is highly recommended by the GDPR regulation. Such techniques reduce risk and assist “data processors” in fulfilling their data compliance regulations. In the engAGE platform, data will be transferred using REST APIs.

Contact person for data management in IRIS Robotics is Andrei Marin.

KRD (and TLU except TLU's technology)

engAGE project (AAL)
October 2021

Data management plan

for the Norwegian partners Karde AS and Tellu AS

In the engAGE project, we will collect anonymous end-user data which will be delivered to the data handling partsers ('behandlingsansvarlig') partners technical University of Cluj-Napoca (coordinator, Romania) and INRCA (responsible for end user studies, Italy) for *overall aggregated analyses and conclusions for improvement of the technology, seen from the end user perspective*.

These data will concern *only* the end user experience that report the engAGE prototype's usability and accessibility in different stages of maturity of the engAGE software/hardware. No information of diagnoses or medication concerning MCI or dementia will be asked for or stored.
The end user participants will therefore be shielded from *any intrusive or unnecessary* questions as far as the project's (one and only) technology goal is concerned.
The Norwegian research will only concern levels of everyday function and IADL (i.e., practical level of performance ability concerning activities of daily living and self-sufficiency), connected to the technology of the engAGE project. Data not directly connected to the improvement of the engAGE technology, will not be posed.

Karde AS will be the *responsible partner* for collecting and creating the aggregated Norwegian data for the consortium. Following aspects cover our data management approach:

- All individual data sheets of the end-user participating in the tests and trials, will be coded and not include any information that allows to identify the individual participant.
- Karde AS or Tellu AS does not keep these data over time neither electronic nor on paper.
- Karde's or Tellu's data sheets with interview data will be destroyed at the end of the project.

Our understanding is that the project coordinator and other project participants will follow all necessary rules and guidelines for data management concerning the project's data.

Contact person for data management in Karde AS is Dr. Riitta Hellman ('personvernombud', appointed for Karde AS by the Norwegian Data Protection Authority). She will act as the contact person for data management for both Norwegian project partners.

TLU

Tellu provides the service for Remote patient monitoring, which includes a backend with data storage, web application for management and mobile application for end users. The service for Remote patient monitoring from Tellu has been developed according to the principles of data protection by design. The following data management plan is adopted from the service's privacy policy. It is directed at the end user of the system, and explains how data privacy is ensured. In the engAGE project, the roles of health organization and health service will be played by either the engAGE consortium as a whole or a project partner.

The purpose of processing personal data

Remote patient monitoring is a service for people who receive health care from a health organization, such as a municipality, a hospital or a GP, and gives you an easy and safe opportunity to keep health personnel continuously updated on general health, special symptoms and other relevant health information. You as a patient will have an agreement with the health organization about use of the service.

Legal authority for the processing of personal data

The following laws regulate which personal data that can be processed and conditions for processing:

- The Health- and care services Act and the Specialist health services Act give the individual the right to receive healthcare from public health services, and the municipalities and the specialist health service have a duty to provide health care to the individual.
- The health personnel Act requires healthcare personnel to document the healthcare given in medical records.
- The Patient Records Act requires health services to give healthcare personnel access to necessary information of good quality about the patient, as well as ensuring the patient's and users' privacy, patient safety and the right to information and participation.
- The Personal data Act and the General Data Protection Regulation (GDPR) impose the health service (Data controller) and suppliers (Data processors) for sound management of personal data, and give the individual patient (the data subject) a number of rights, including the right to access registered personal data, as well as correction and deletion of their data.
- The Patient and user rights Act gives the individual the right to access information that is necessary to gain insight into their health condition and content of the health care provided.

Responsible for data processing

The health service is responsible for providing health services to its inhabitants/patients and is data responsible for all processing of personal data related to the service. The data responsibility entails the responsibility for control measures to ensure that no one has unauthorized access to the personal data.

Your rights

You have the right to access your own data. All relevant information is available to you via the patient application. This applies to general personal information, careplans, submitted information and sensor measurements, health personnel's notes to you, log of who has had access to your personal data etc.

If any data is incorrect, you have the right to have the data corrected, as well as the right to have information deleted if you believe the data should not have been registered. Contact your healthcare provider if this is the case.

Processing of personal data

The following describes at a general level how personal data is processed:

- You log in using a secure authentication server. Neither the healthcare service nor Tellu has access to your password or PIN code.
- No personal data is stored on your mobile phone/tablet.
- No personal data is stored on the health personnel's PC/tablet.
- All communication towards the service's central data solution is encrypted.
- All personal data is stored in Norway, encrypted in the health service' health archive at Tellu on behalf of the health service.
- Personal data is stored in the service's central data solution until the health service decides that it should be deleted.

Tellu's responsibility as supplier and data processor

Tellu is the health service's supplier of software and medical sensors and performs the role of Data Processor in accordance with the data processor agreement between Tellu and the health service. Tellu has developed the service and performs ongoing maintenance and operational services, but has no access to personal information unless the health service submits a written request for technical assistance.

Tellu's subcontractor

Microsoft Azure – owns and operates data center, hardware and backups. Does not have access to personal data.

Report deviation

If you suspect unfortunate or problematic processing of personal data in the service, you must report deviations directly to the health service that is responsible for the health care where this service is included. The health service will then initiate actions that are necessary to investigate and close deviations.

TUC

Data management plan for Technical University of Cluj-Napoca (TUC)

During the research and development phases of the project lifetime each technical partner will provide its own infrastructure for hosting the developed components, processing, and storing personal data collected through the engAGE platform in Romania and Norway into Iris, TUC, Tellu and KARDE premisses. After the end of the project when exploitation, IP and business plans will be established it will be decided how hosting and data storage will be managed under a live production environment. Thus, a critical area of security is the servers (cloud or on-premises) where the solutions will be deployed, or on which data will be stored. These need to be provided with physical and logical protection.

TUC will store and process data in its premises in Cluj-Napoca, Romania. TUC has allocated a specific state of the art server for handling engAGE data which is isolated from other research and development activities done in other projects implemented by TUC.

Physical security measures for protecting the data stored and processed on the server:

- The server is in a secured area with fire protection, proper ventilation and cooling
- Only authorized personnel have access to the server room (TUC team researchers)
- Access in the server room is done based on secure key cards, that are kept in a locked office when not used.
- The server room has an allocated alarm system which is permanently activated when authorized personnel are not in the room. Passwords for alarm system are known only by engAGE TUC personnel.
- The server has backup batteries for power outage.

Logical security measures for data protection on TUC server:

- The server HDDs use RAID techniques for backing up data in case of one HDD failure
- The operating system is a Linux kernel is protected through authentication and authorization. Only engAGE TUC personnel has the credentials for accessing the OS level services.
- The communication network uses mechanisms of comprehensive network protection against intrusion such as: IPS (Intrusion Prevention System), firewall and network antivirus filter.
- Remote access to the server is possible only through secured VPN connections and only TUC personnel from the project have credentials and details how to access it.
- The developed services and components will be isolated at the OS level using Docker containers.
- The DB servers deployed on the physical server will be protected against intrusions using password authentication. DB passwords are known only by TUC engAGE personnel.

Among the IT security techniques available, data pseudonymisation or anonymisation is highly recommended by the GDPR regulation. Such techniques reduce risk and assist "data processors" in fulfilling their data compliance regulations. The data handled in TUC premisses will be received in anonymised format from the end-user sites in Italy (INRCA), Swizerland (HUG) and Norway (KARDE). In the engAGE platform, data will be transferred using REST APIs. To secure data transmission, we will use the HTTPS protocol that uses the TLS protocol to encrypt data. Security of data access or transfer will be achieved using a firewall with appropriate security rules. Also, TUC data handling will consider solutions that eliminate or significantly reduce the system's vulnerability to attacks as recommended in the Open Web Application Security Project (OWASP).

TUC DMP