TOILET FOR ME

AAL PROGRAMME

D2.1

Legal considerations and recommendations on ethical compliance, data collection, privacy and security

Project Number	AAL-2019-6-116-CP
Project Name	Toilet4me2
Duration	1 Mar 2020 – 28 Feb 2023
Coordinator	TU Wien
Document ID	D2.1
Release Number /Date	Version 1 / 30 June 2020
	V1a / 23 Aug 2021 (typos corrected)
Checked and released by	TUW
Document Type	Project Deliverable
Original Due Date	PrM 4
Dissemination Level	Public
Main Editor	OSF + CDC
Contributing Partners	all

Abstract

This document is the deliverable D2.1 "Legal considerations and recommendations on ethical compliance, data collection, privacy and security" of the Toilet4me2 (Study on supporting active living in (semi-) public environments by suitable toilets) project (short also "T4ME2") within Call 2019 of the AAL Programme.

This deliverable summarises and defines the ethical, legal and data protection principles, most notably those derived from the EU GDPR, the Charter of Fundamental Rights of the European Union and relevant Member States legislation that needs to be respected by the system developers and the pilot sites throughout the entire project.

The Toilet4me2 project is Co-funded by the European AAL Joint Programme and national funding agencies in Austria, Belgium, Hungary, Netherlands, Poland and Romania.

Version	Date	Changes	Name	Organisation
1	30.06.2020	First complete version issued	C. Dantas, N. Machado, F Rodrigues, M Kubecka, M Trakul	CDC/OSF
1a	23.8.2021	Typos corrected		
Review Date: 30.6.2020 OSF+TUW				

List of Authors

Magda Kubecka, Marta Trakul - Masłowska – OSF

Carina Dantas, Natália Paes Leme Machado, Flávia Rodrigues - CDC

Content

1 Executive Summary

This deliverable - D2.1 Legal Considerations And Recommendations On Ethical Compliance, Data Collection, Privacy And Security - is the first outcome of task 2.1 Ethical guidelines approval and compliance, that aims to define the ethical, legal and data protection principles, most notably those derived from the EU GDPR, the Charter of Fundamental Rights of the European Union and relevant Member States legislation that needs to be respected by the system developers and the pilots sites throughout the entire project.

This report presents information regarding the ethical and deontological framework for the system's research and development, its application to more fragile target groups, as well as the relevant principles in the design and implementation of ICT tools in the socio-sanitary context. Also, some legal considerations and recommendations on ethical compliance, data collection, monitoring, storage, and security of personal data are presented.

The document will also establish the Project Ethics Committee. Representatives of all end-user groups will be involved in an Ethics Committee that will assess the adequacy and easy understanding of all materials and support the supervision of all Ethical issues raised during the project.

In conclusion, a compilation of recommended good practices will be presented, resulting in guidelines that should be taken into consideration throughout the project.

2 Legal Framework

The legal and ethical challenges regarding the development and implementation of ICT tools, which will be able to respond to the demands and desires of an ageing European population, are currently a relevant and actual concern. This legal framework is even more challenging in projects such as Toilet4me2, that involve multiple sites and need to combine different European countries with multi-national normative and rules. The purpose of collecting this legislation is to ensure that all partners have an initial idea of what is required in legal terms and what should be put into practice. To facilitate this, since the legislation is very broad and diverse, this information will be compiled at the end of the deliverable, in the form of guidelines.

Departing from a brief thematic desk research on the existing legislation and best practices, this chapter will be divided into International Framework, where two sections will be described: soft law and hard law. After these, the national legislation of all pilot sites involved in the project will also be presented and analysed.

2.1 International framework

The project aims to support people who normally need assistance when using a standard toilet. This assistance can be provided by a combination of a motorized toilet seat with ICT components and optional add-ons. Building on this project objective, the consortium saw the need to consult international law, specially, the European one, to ensure that all aspects of it were respected.

The term soft law is used to refer to agreements, principles and declarations that are not legally binding and whose instruments are predominantly found in the international sphere, e.g. UN General Assembly resolutions. As opposed to Hard law which generally refers to legal obligations that are binding on parties involved, and which can be legally enforced before a court (e.g. the GDPR)[1].

In the following sections, we analyse in detail the legal framework to be considered during the creation of the system and the development of the pilots.

2.1.1 Soft law (Participant human rights; values and principles; standards and best practices)

At the European level, the guidelines established in the Declaration of Helsinki are the standard framework to validate ethical, security and privacy issues. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data[2]. As an ethical, legal and regulatory standard, this declaration is above other regulations. It was originally adopted in June 1964 in Helsinki, Finland, and has

[1] European Center for Constitutional and Human Rights. Glossary. Hard Law / Soft Law. Available at: https://www.ecchr.eu/en/glossary/hard-law-soft-law/

[2] World Medical Association. WMA Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

undergone seven amendments since then (the most recent being at the General Assembly in October 2013). The declaration is addressed primarily to physicians, all the while encouraging others connected to research involving human subjects to adopt these principles.

Regarding the importance of this principles, the Toilet4me2 project highlighted these values to better understand them:

Principle	Explanation
Human rights	As part of **individual's rights**, researchers, technical partners and end-users' organisations must protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information from the users/participants (Article 9 and 24).
The respect for the individual	The investigator's duty is solely to the patient or volunteer, and while there is always a need for research, **the subject's wellbeing must always take precedence over the interests of science and society**. (Article 8) It means that the most general and relevant principle is the **respect for the individual.** **Participants 'rights and interests cannot be left aside as they are more important than the research itself.**
Vulnerable Groups	The recognition of the increased vulnerability of individuals and groups demands **special vigilance and protection.**
Participant's protection increased with Informed Consent	The informed consent (Article 25) integrates the participant's rights, especially the **right of information**, to be able to decide their participation (Article 22).
First Ethic and then Law	Lastly, it is important to indicate that the Declaration of Helsinki highlights the **ethical considerations**, which **must always take precedence over laws and regulations** (Article 10).

Table 1: Helsinki Declaration Principles

Having these principles as basic grounds, other relevant international legislation must be observed, to reassure protection and compliance of ethical aspects:

- Nuremberg Code: created more than 70 years ago following the World War II experiments, this written document established 10 ethical principles for protecting human subjects, including principles such as the following:
    - Voluntary consent of the human subject is absolutely essential;
    - There must be a scientific justification for experimentation;
    - Participants must be protected from all unnecessary physical, mental suffering, injury

- Universal Declaration of Human Rights
- European Convention on Human Rights
- Charter of Fundamental Rights of the European Union, and in particular:
  - Article 1 (Human dignity)
  - Article 3 (Right to the integrity of the person)
  - Article 7 (Respect for private and family life)
  - Article 8 (Protection of personal data)
- Treaty on European Union, and in particular Article 6 of the common provisions concerning respect for fundamental rights (EU, 1992)[3];
- Convention of the Council No. 5 for the protection of human rights and fundamental freedoms (COE, 1950) - Art. 8[4]
- Universal Declaration on Bioethics and Human Rights (UNESCO, 2006)[5]
- Convention No. 108 of the Council of Europe for the protection of individuals about automatic processing of personal data (COE, 1981)[6].
- The Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data repeals Council Framework Decision 2008/977/JHA, entered into force on 5 May 2016 and EU Member States have to transpose it into their national law by 6 May 2018. (EU, 2016)[7]
- Directive 97/66 EC concerning the processing of personal data and the protection of privacy in the telecommunications sector. (EU, 1997)[8]
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic

[3] European Union (EU), 1992. Treaty on European Union. Retrieved from: https://europa.eu/european-union/sites/europaeu/files/docs/body/treaty_on_european_union_en.pdf

[4] Council of Europe (COE), 1950. Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocols No. 11 and No. 14. Retrieved from: https://rm.coe.int/1680063765

[5] United Nations Educational, Scientific and Cultural Organization (UNESCO), 2005. Universal Declaration on Bioethics and Human Rights. Retrieved from: https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights

[6] Council of Europe (COE), 1981. Convention 108: Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Retrieved from: https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/108

[7] European Union (EU), 2016. Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016L0680

[8] European Union (EU), 1997. Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31997L0066

communications sector. (EU, 2002)[9]

- Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC; (EU, 2006)[10]
- Directive 99/5/EC: Radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. (EU, 1999)[11]
- Council of Europe Convention 108: Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. (CE, 1981)[12]
- The "European Group on Ethics in Science and New Technology (EGE — more specifically, through "Opinion n° 26 - 22/02/2012 - Ethics of information and communication technologies, more related to the protection of privacy and protection against personal intrusion in ICT. (EU, 2012)[13]
- Article 29 Data Protection Working Party, Opinion 4/2007 on the concept of personal data. (EU, 2007)[14]

2.1.2 Hard law (Personal data privacy and security; data protection - GDPR)

The present section focuses on hard law. One of the main instruments currently observed in research involving human beings is the EU General Data Protection Regulation (GDPR), which brings all relevant aspects regarding personal data privacy, security, and data protection.

The GDPR Regulation 2016/679[15] is the most important change in data privacy regulation in 20 years. Its main objectives are to harmonize data privacy laws across Europe, to protect and to empower all EU citizens' data privacy and to reshape the way organizations across the region approach data privacy. To guarantee that all the data collected complies with the GDPR

9 European Union (EU), 2002. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications). Retrieved from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32002L0058

10 European Union (EU), 2006. Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC. Retrieved from: https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32006L0024

11 European Union (EU), 1999. Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31999L0005

12 Council of Europe (COE), 1981. Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Retrieved from: https://rm.coe.int/1680078b37

13 European Union (EU), 2012. European Group on Ethics in Science and New Technologies (EGE)

Retrieved from: https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/ege_en

14 European Commission (EC), 2007. Opinion 4/2007 on the concept of personal data. Retrieved from: https://www.gpdp.gov.mo/uploadfile/others/wp136_en.pdf.

15 General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

requirements is fundamental when addressing the ethical principles.

The GDPR has an extended jurisdiction - extraterritorial applicability. It applies to all organisations processing the personal data of data subjects residing in the European Union, regardless of their location.[16]

The GDPR sets out seven key principles that shall lie at the heart of Toilet4me2's approach to processing personal data:

Lawfulness, fairness and transparency	The collection of personal data must be conducted in a fair manner, ensuring it was not obtained under false pretense and satisfying reasonable expectations as to how the data will be used
Purpose limitation	Data collected only for specified, explicit and legitimate purposes
Data minimisation	The data collected must be adequate to the purposes for which they are processed

[16] General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

Accuracy	The data collected must be accurate and, where necessary, kept up to date
Storage limitation	Data must be kept in a way which grants identification of data subjects for no longer than necessary
Security	The data must be processed to ensure appropriate security of personal data, including protection against unauthorised or unlawful access
Accountability	Data controllers have to be able to demonstrate they are GDPR compliant.

Table 2: GDPR Key principles

Data protection legislation concerns personal data - "any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical physiological, genetic, mental, economic, cultural or social identity of that natural person" (Art. 4.1 GDPR)[17]. It concerns the processing of such personal data, where processing means "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction" (Art. 4.2).[18]

Based on these principles and legislation, this consortium will take all necessary cautions to guarantee confidentiality of any of the data collected.

Despite this, to completely understand the GDPR regulations and ensure they are well applied in the project, some highlights are provided, namely regarding this regulation novelties in relation to previous ones:

- **The concept of "privacy by design"** is another challenging aspect of the GDPR. This principle implies that all the data protection and privacy issues must be considered not only for the trials but for the different phases of the technological development. (EU,

[17] General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

[18] General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

2016). All information gathered must be kept confidential and be secured against unauthorized access. [19]

- **The need for consent** is the highest requirement in trials, research involving health and care provision and technological development.)[20]
- **Confidentiality and Protection of Personal Data**. In principle only already anonymised data will be processed and, therefore, no personal data will be used in relation to specific users. The name of the person will not be connected to other characteristics (e.g. age, sex, nationality, health condition, etc.). The connection can be made through a number where the "key" to the participant is. Participants will be recorded only if they provide consent. All this information falls under the European legislation for the lawful processing of personal data, in connection with the concept of pseudo anonymization.[21]
- **The "right to be forgotten".** With this safeguard, the participants or users may ask to erase all their data.[22]

Based on these principles and legislation, this consortium will take all necessary cautions to guarantee the confidentiality of any of the data collected.

As described in the D3.1 – Evaluation protocol and test plans:

- all information gathered will be kept confidential and be secured against unauthorized access.
- all participants will be informed about the study and their planned involvement in the study so they can make an informed choice.
- every evaluation step will be pre-validated before end users are involved
- the project trial personnel members will manage the data, focusing on its protection.
- the collected information will be transferred for analyses only after pseudonymization.
- if data is shared with other researchers and research institutions outside this consortium, data will be completely anonymized.

2.2 National framework

In addition to the European legislation mentioned above, there is also the need to be aware of the national legislation regarding field trial participants, namely concerning human rights,

[19] General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

[20] General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

[21] General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

[22] General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

integrity, personal data privacy and security, ethics reviews and clearance and professional regulation of each country where the pilots will take place. For this purpose, a survey was elaborated and distributed to the pilot sites to collect structured information and relevant links.

The answers are depicted in the following sections.

2.2.1 Dutch legislation

Participant human rights

- The Dutch Constitution is one of two fundamental documents governing the Netherlands as well as the fundamental law of the European territory of this country. The article 11 describes individual rights: "Everyone shall have the right to inviolability of the person, without prejudice to restrictions laid down by or pursuant to Act of Parliament."
- "The Netherlands Code of Conduct for Scientific Practice", from the Association of Universities in the Netherlands is the main document regarding the scientific practice. Although this legislation and regulations are not fully applicable to this project, as it is not medical research or research in which the participants are subject to a specific behaviour, the principles of the WMO and the Code can be applied. The most important principles in this Code are:
- Scrupulousness,
- Reliability,
- Verifiability,
- Impartiality and
- Independence
- The Netherlands' Code of Conduct for Research Integrity published in 2018 is another good example to use for guidance. This document is a Code of Conduct for researchers and institutions in the Netherlands, but also respects the scope of international framework documents[23].
- The code of 'Good Behaviour' (*code van Goed Gedrag* in Dutch) is another document that must be taken into consideration. The rights relating to the medical treatment contract lay down the rights of patients. Such a retrospective examination is subject only to the regulation on the medical treatment agreement from the Dutch Civil Code (Book 7, title 7, section 5 of the Dutch Civil Code), also referred to as the Medical Treatment Agreement Act (WGBO).

Personal data privacy and security

- The *Burgerlijk Wetboek* (or BW) is the Civil Code of the Netherlands. The Dutch Civil Code was substantively reformed in 1992 and deals with, for example, the rights of natural persons[24]. In this sense, Book 7 describes necessary consent of the patient, in

[23] https://www.vsnu.nl/files/documents/Netherlands%20Code%20of%20Conduct%20for%20Research%20Integrity%202018.pdf

[24] http://www.dutchcivillaw.com/

the medical treatment, but could be applied for also researches: Article 7:450 "The consent of the patient is required for actions to be performed in the implementation (performance) of the medical treatment agreement."

- The Personal Data Protection Act(*Algemene Verordening Gegevensbescherming* (AVG) in Dutch) determines the guidelines for data processing. For example, that personal data shall be processed in accordance with the law and in a proper and careful manner and personal data shall be collected for specific, explicitly defined, and legitimate purposes[25]. Due to its compatibility with GDPR, it is extremely important legislation for this project.

Professional regulations

- The Federa (Foundation Federation of Dutch Medical Scientific Societies) aims to represent scientific biomedical societies by promoting interdisciplinary communication through an annual thematic conference and self-regulation. This federation has also drawn up the Code of Conduct for Health Research, that is a manual for the use of (anonymous) personal data in scientific research.
- The Netherlands Bar (Nederlandse orde van advocaten, NOvA) is the professional organisation of the legal profession. The NOvA was established by the Act on Advocates (Advocatenwet) with effect from 1 October 1952.
- VERSEN is the Dutch National Association for Software Engineering. Its mission is to bring together researchers, educators and practitioners in the field of software engineering in The Netherlands, who share the common goals of advancing the field or software engineering, raising public awareness of challenges and opportunities of the field, acquiring funding for ground-breaking research, and transferring academic results to broader society.

2.2.2 Polish legislation

Participant human rights

- The Polish Constitution – published on April 02, 1997. Regarding pilot´s participants' human rights is possible to highlight the articles: General principles of the freedoms, rights and obligations of persons and citizens – art. 31 - 2 "Everyone shall respect the freedoms and rights of others. No one shall be compelled to do that which is not required by law."; regarding personal freedoms and rights – art. 39 "No one shall be subjected to scientific experimentation, including medical experimentation, without his voluntary consent."; art. 41 "Personal inviolability and security shall be ensured to everyone. Any deprivation or limitation of liberty may be imposed only by accordance with principles and under procedures specified by statute."
- On the topic of older people's protection there is the Social policy towards older persons 2030. The creation of a comprehensive Programme in the field of senior policy will allow to systematise and improve the activities of public institutions for older people in Poland.

[25] https://www.ivir.nl/syscontent/pdfs/145.pdf

These solutions will also contribute to a significant improvement in the quality of life of older people and allow them to stay independent as long as possible[26].

Personal data privacy and security

- The Act of August 29, 1997 about Protection of Personal Data[27] is highlighted as a good practice and an important document in this country.
- Article 1

Any person has a right to have their personal data protected.

The processing of personal data can be carried out in the public interest, the interest of the data subject, or the interest of any third party, within the scope and subject to the procedure provided for by the Act.

- Article 23
- Paragraph 1. The processing of data is permitted only if: the data subject has given their consent, unless the processing consists in the erasure of personal data, the processing is necessary for the purpose of the legitimate interests pursued by the controllers or data recipients, provided that the processing does not violate the rights and freedoms of the data subject.
- Paragraph 2. The consent referred to in paragraph 1, point 1 may also be applied to future data processing, on the condition that the purpose of the processing remains unchanged.
- Article 24
- Paragraph 1. In case where personal data are collected from the data subject, the controller is obliged to provide a data subject from whom the data are collected with the following information:

the address of its seat and its full name, and in case the controller is a natural person about the address of his/her residence and their full name,

the purpose of data collection, and about the data recipients or categories of recipients, if they're already known at the date of collecting

the existence of the data subject's right of access to his/her data and the right to rectify these data,

whether the replies to the questions are obligatory or voluntary, and in the case of obligation, inform the data subject about its legal basis.

- Article 26
- Paragraph 1. The controller performing the processing of data should protect the interests of data subjects with due care, and in particular to ensure that:

the data are processed lawfully,

the data are collected for specified and legitimate purposes and no further processed in a way incompatible with the intended purposes, subject to the provisions of paragraph 2 below,

the data are relevant and adequate to the purposes for which they are processed,

the data are kept in a way which permits identification of the data subjects for no longer

[26] https://www.unece.org/fileadmin/DAM/pau/age/country_rpts/2017/POL-Report-EN.pdf

[27] http://www.en.pollub.pl/files/17/attachment/96_The-Act-of,Personal,Data,Protection,1997.pdf

than necessary and for no other purposes other than those for which they were processed.

- Article 47. Transfer of Personal Data to a Third Country
- Paragraph 1. The transfer of personal data to a third country may take place only, if the country of destination ensures at least the same level of personal data protection in its territory as that in force in the territory of the Republic of Poland.
- Paragraph 3. Nevertheless, the controller may transfer the personal data to a third country provided that:

the data subject has given his/her written consent,

the transfer is necessary for the performance of a contract between the data subject and the controller or takes place in response to the data subject's request,

the transfer is necessary for the performance of a contract concluded in the interests of the data subject between the controller and another subject.

Professional regulations

- The Polish Federation of Engineering Associations is the largest and most significant Polish association representing professional engineers and technicians. It works for the benefit of science, technology and the economy of the Republic of Poland, supporting the creative efforts of Polish engineers and technicians.[28]
- Act of Parliament on Legal Advisers (ustawa z dnia 6 lipca 1982 r. o radcach prawnych) The Law on Advocates (ustawa z dnia 26 maja 1982 r. Prawo o adwokaturze)[29]
- Code of Ethics - The first Polish Code of Ethics, which recommended supervision over guidelines, programs and compliance with ethical and deontological principles of new methods and drugs in the pursuit of scientific knowledge, was the Collection of Ethical and Deontological Rules for the Polish Doctor approved in 1977. These guidelines were revised at the Extraordinary National Assembly of Delegates of the Polish Society of Medicine in Szczecin on 22 June 1984. The Collection of Ethical and Deontological Rules for the Polish Doctor was passed and recommended that new methods or new drugs would be introduced only by highly qualified teams and only in units entitled to do so, after obtaining prior permission from the relevant Ethics Committee. In 1989, Poland re-established the medical council which had been abolished in 1950. Two years later, a new version of the Code of Medical Ethics was created, in which art. 44 of Chapter II "Scientific Research and Medical Experiments" is stated that: "The design of each experiment on human subjects should be clearly defined in writing and submitted for the assessment of an independent ethics Committee in order to obtain consent"[30]

2.2.3 Romanian legislation

Participant human rights

[28] https://not.org.pl/

[29] https://www.ccbe.eu/NTCdocument/en_poland_law_on_adv1_1188889310.pdf

[30] http://www.eurecnet.org/information/poland.html

- The Constitution of Romania[31] is the fundamental governing document of Romania that establishes the structure of its government, the rights and obligations of citizens, and its mode of passing laws. It stands as the basis of the legitimacy of the Romanian government. Adopted on 21 November 1991, it was approved on 8 December 1991 in a national referendum and promulgated on the same day. The fundamental rights are described in Title II:
- Right to life, to physical and mental integrity: Article 22 "The right to life, as well as the right to physical and mental integrity of person are guaranteed."
- Individual freedom: Article 23 "Individual freedom and security of a person are inviolable."
- Protection of disabled persons: Article 50: Disabled persons shall enjoy special protection. The State shall provide the accomplishment of a national policy of equal opportunities, disability prevention and treatment, so that disabled persons can effectively participate in community life, while observing the rights and duties of their parents or legal guardians.
- The body of Romanian law that defines the entire Romanian civil law system is codified under the title of Codul Civil Român (Engl. The Romanian Civil Code), initially published in July 2009, but enacted on October 1, 2011 (See Monitorul Oficial no. 505 of July 15, 2011).[32]

Personal data privacy and security

- Regarding the protection of personal data, besides the GDPR, Romania must observe law no. 363 from 28 December 2018:
- Article 1

  This law regulates the processing of personal data for the purpose of carrying out activities of prevention, discovery, investigation, prosecution and combating of crimes, execution of punishments, educational and security measures, as well as maintaining and ensuring order and safety. by the competent authorities, within the limits of the powers established by law.

  The processing of personal data for the performance of activities of maintaining and ensuring public order and safety is carried out only if they are provided by law and are necessary to prevent danger at least to the life, bodily integrity or health of a person or property as well as for combating crime.
- Article 2

  The purpose of this law is to protect the freedom and fundamental rights of individuals, in particular the right to protection of personal data.

  This law establishes the conditions under which the free movement of personal data is executed in order to carry out the activities provided in the article.
- Article 5: Personal data must be:
  - processed legally and equitably;

[31] http://www.cdep.ro/pdfs/reviz_constitutie_en.pdf

[32] https://www.nyulawglobal.org/globalex/Romania1.html#_5.4_Civil_law

  - collected for determined, explicit and legitimate purposes and not to be processed in a manner incompatible with these purposes;
  - adequate, relevant and not excessive in relation to the purposes for which they are processed;
  - accurate and, if necessary, up to date; all reasonable steps must be taken to ensure that personal data which are inaccurate in regard to the purposes for which they are being processed, are deleted or rectified without delay;
  - processed in a way that ensures adequate security of personal data, including protection against unauthorized or illegal processing and against accidental loss, destruction or damage, by taking appropriate technical or organizational measures.
- Article 9

  Regarding personal data processing in the form of transfer to recipients, the competent authority transferring personal data shall have an obligation to inform the recipient of personal data of the specific processing conditions and the obligation to comply with them. in which such conditions are imposed by law.

  The recipient of personal data has an obligation to comply with the specific processing conditions communicated in accordance with the provisions of par. (1).

  In the event of the transfer of personal data to recipients in Member States of the European Union or to agencies, offices and bodies set up in accordance with Chapters 4 and 5 of Title V of the Treaty on the Functioning of the European Union, no specific conditions may be imposed.
- Law 206/2004 on good conduct in scientific research, technological development and innovation
- Law 677/2001 on the protection of personal data

Professional regulations

- The organization of the liberal profession of the lawyer was made for the first time in Romania by the Law of December 6, 1864 for the establishment of the bar.
- Code of Deontology of the Romanian College of Physicians. The present code includes the compulsory rules of behaviour concerning the doctor's practice of rights and professional duties.[33]

2.2.4 Belgian legislation

Participant human rights

- The Belgium Constitution dates to 1831. Regarding fundamental rights, the Belgium Constitution determinates that: Article 11: "Enjoyment of the rights and freedoms recognised for Belgians must be provided without discrimination. To this end, laws and federate laws guarantee among others the rights and freedoms of ideological and

[33] http://www.ceom-ecmo.eu/sites/default/files/documents/romanian_code_of_medical_deontologypdf.pdf

philosophical minorities."

- Codes of Ethics For Scientific Research In Belgium is a joint initiative and establishes the major principles of ethically justified scientific practice. A code of ethics offers advantages in relation to legal or statutory standards. Indeed, it is impossible to elaborate precise rules covering all cases and circumstances.[34]

Personal data privacy and security

- In Belgium, since 01 May 2004, the law of 07 May 2004 (published in the Belgian Official Gazette on 18 May 2004) on experiments on the human person must be applied. It is important to distinguish between interventional and non-interventional research.
- Non-interventional study (referred to in the law as a "non-interventional trial"): Research in which the drugs are prescribed in the usual manner, in accordance with the conditions laid down in the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not predetermined by a trial protocol, but is part of normal medical practice and the decision to prescribe the drug is entirely separate from the decision to allow a patient to participate in the study. The patient in question does not need to undergo any additional diagnostic or monitoring procedure and epidemiological methods are used to analyse the results obtained.
- Interventional study: This includes any human study (referred to by law as an "experiment") that deviates from normal standard diagnostics or standard therapy. Some examples: An additional blood sampling; An RX; Administering a drug in a different dose or formulation, for a different indication, randomising.
- The law applies to both interventional and non-interventional studies, except for retrospective studies.

Professional regulations

- The Belgian Society for Medical Informatics ("MIM")[35] was established in 1974 to promote and develop medical information science and technology in Belgium.
- The Ordre des Barreaux Francophones et Germanophone (OBFG) groups together all the local bars of the French-speaking and German-speaking communities in the country. The Orde van Vlaamse Balies (OVB) is the umbrella organisation for the local bars of the country's Dutch-speaking community.

2.3 Ethical approvals by regional or national Ethics Committees.

All data collected, shared and analysed during the project will strictly follow the European legal and ethical regulation. Research ethics requires that all research involving human participants, personal data, or human tissue should be reviewed, and research ethics approval obtained, before the beginning of the trial period Each trial site partner will ask for approval from the respective Ethical Committees, since the Toilet4me2 project involves specific ethical issues, due to the main aim of the study - to test and validate the developed ICT tools through

[34] https://www.kuleuven.be/english/research/integrity/practices/belspo-code
[35] https://www.bmia.be/en/home/

the Human-Technology interaction. The rules and processes regarding each national ethical Committee are described below.

2.3.1 Dutch Ethical Committee

The Dutch Ethical Committee is the Medical Committee of the Utrecht Hospital. To submit a request to this Committee, it is necessary to fill in a form to see what kind of clearance is required.

Research falls under the WMO if it meets the following two conditions:

- There is talk of medical scientific research and
- Persons are subjected to actions or rules of conduct are imposed on them.

If in doubt, you can submit the (non-) WMO form to the METC. The form can be downloaded from this page https://www.metcutrecht.nl/nl/is-toetsing-nodig .

The METC only assesses based on the information in the form whether the investigation falls under the scope of the WMO. Only attachments that may be relevant for this, such as questionnaires, can be attached.

There is no substantive test of the research itself. If the METC decides that the research is not subject to the WMO, the researcher will receive a statement that the research is not subject to the WMO. Other legislation may apply, like GPDR (AVG in Dutch) and the rules of the test sites self. An overview of types of research not subject to the WMO and relevant legislation can be found on the CCMO website

Whether research that probably does not fall under the WMO should be submitted to a METC depends on the policy of the institution where the research is carried out. Check this with the research agency of the institution concerned.

The time that the ethical approval usually takes, depending on when the Board meets, can consist of a couple of weeks. Summer holidays might cause a delay.

In Toilet4me2 case, the METC informed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the above mentioned study and that therefore an official approval of this study by the MREC Utrecht is not required under the WMO. This letter is included in this document as an annex.

2.3.2 Polish Ethical Committee

The Committee is based at the University of Warsaw.

There is a clear list of templates and form that the Polish partners need to collect (at the website). The Committee is focused on communication with the users / study participants - to keep them informed, to make sure they understand the project and to make clear rules regarding resignation during the project

1. Application with study description. It should include: - title of the project and its duration - people involved in the project, in the case of persons without a doctoral degree also information about the academic supervisor - description of the project in accordance with the guidelines (justification of the purpose of the study, course and methodology of the study, characteristics and selection of the sample, benefits of the

study , risks and burdens associated with participation in the study) - a description of the ethical aspects of the study in accordance with the guidelines (data processing and protection, conflict of interest, other ethically significant aspects of the study)

2. The pattern of the consent of study participants to participate in the study.

3. Model consents of study participants for the processing of personal data [applies only to studies in which personal data is collected and processed]

4. Model information for study participants on the processing of personal data [applies only to studies in which personal data is collected and processed]

5 Information for study participants (explaining its course, risk, contraindications, etc.)

6. Materials used during the study, in particular: - questionnaires used - examples of stimuli (if they are of a visual or verbal nature)

The time that the ethical approval usually takes is from 3 to 4 weeks. The Committee collects applications until September 30 but they can start proceeding earlier if it is an urgent situation).

2.3.3 Romanian Ethical Committee

The Romanian Ethical Committee is the National Council for Ethics of Scientific Research, Technological Development and Innovation (CNECSDTI), that is a consultative body, without legal personality, attached to the state authority for research and development (art. 5-8 of Law 206/2004).

To the ethical requirement, the Romanian partners should fulfil a template to application with study description. It should include:

1. title of the project and its duration - people involved in the project, description of the project in accordance with the guidelines (justification of the purpose of the study, course and methodology of the study, characteristics and selection of the sample, benefits of the study , risks and burdens associated with participation in the study) - a description of the ethical aspects of the study in accordance with the guidelines (data processing and protection, conflict of interest, other ethically significant aspects of the study)

2. The pattern of consent of study participants to participate in the study.

3. Model consents of study participants for the processing of personal data [applies only to studies in which personal data is collected and processed]

4. Model information for study participants on the processing of personal data [applies only to studies in which personal data is collected and processed]

5. Information for study participants (explaining its course, risk, contraindications, etc.)

6. Materials used during the study, in particular: - questionnaires used - examples of stimuli (if they are of a visual or verbal nature)

Depending on the complexity of the ethical issue and the number of projects under review at the time, the approval can take between 3 to 6 weeks.

Beia Consult International corresponded with The Romanian Ethical Committee which assured that the project's internal ethics procedure is enough to properly cover all the ethics aspects of Toilet4me2. This document includes an annex of Beia's ethics procedure.

2.3.4 Belgian Ethical Committee

The documents that need to be taken into account when submitting the ethical approvement are: - Application form Document A

- Protocol
- Researcher's File (Researcher's Brochure)
- Recent insurance certificate for the study, stating the amount, stating the coverage and stating the policy is conforming the Belgian Law on experimentation on the human person dd. 7/05/2004, art. 29.
- Financial agreement, or if this is not available, then use the client's Budget Proposal (if- the Budget Proposal is submitted and the amount of the financial agreement is higher than the- Budget Proposal, the financial agreement must be submitted for approval to the Committee on Medical Ethics and a signed agreement must be provided to the leading ethics committee as soon as available.
- Request for authorization of a clinical trial on a medical product for "Request for authorization of a clinical trial on a medical product for human use to the competent authorities and for the opinion of the ethics Committees in the community' (www.EMEA.int.eu: EudraCt database)
- Dutch-language Information and Consent Form
- Information and consent form(s) in other languages (if applicable)
- CV and GCP-certificate of the researchers
- All documents directly related to the patient (questionnaires[1], flyers, ...)
- Cover letter signed by the PI of the site were the submission is done (not signed by the firm or the Belgian coordinating PI of another site)
- Receipt showing attached documents

Applications submitted on Friday and/or the day before a public holiday after 12 noon will automatically receive the day stamp of the next working day. The ethics committee is obliged (by law) to give an opinion at the latest 28 days after validation of a dossier. In case of a Phase I trial, this delay is 15 days. When it is a multicenter study the legal timelines can be delayed since all ethics committees did not receive the dossier at the same time (simultaneously submission did not occur)

3 Ethical Framework

The purpose of this chapter is to provide a comprehensive overview of the Ethical challenges within the Toilet4me2 project, with the main purpose of delivering guidelines for the implementation sites and technical partners.

Within this context, this chapter will mainly provide the dimensions and challenges that need to be acknowledged and understood by all Toilet4me2 partners, enabling the researchers and project partners to incorporate the best possible behaviour towards a successful and reliable implementation of the project's solution.

Ethics in Toilet4me2 will analyse some of the relevant dimensions for the project, following the scheme provided by Anunciação (2014) and (2016): personal ethics, professional ethics, organizational ethics, economic ethics and societal ethics[36].

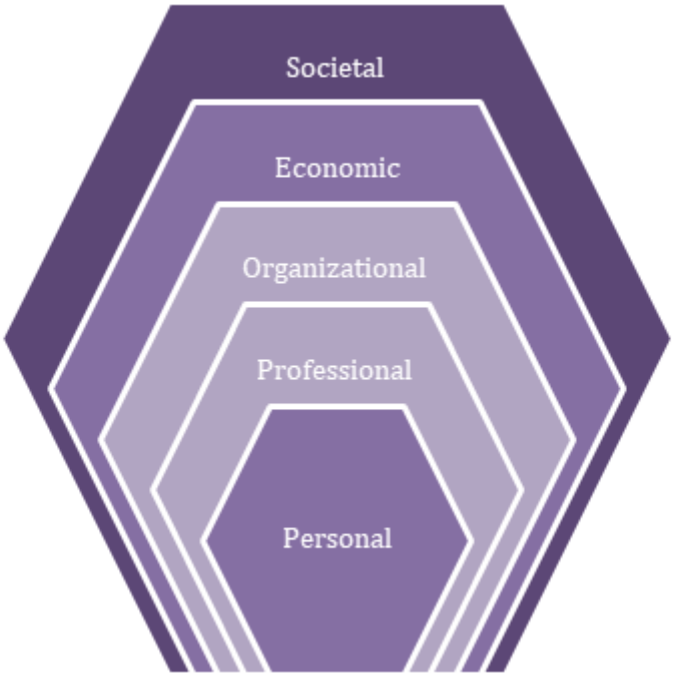


Table 3: Ethics relevant dimensions

In personal dimension, the ethics and privacy are fundamental issues to be addressed in ICT development, not only to improve the technology security but also to guarantee that the project findings are scalable and appropriate for the market, which of course implies that they comply with EU and national regulations. In professional dimension, it is relevant to highlight that all the technological features and characteristics must be user-centred and considerer the user opinion during the system development and integration. In the organizational aspect,

[36] Anunciação, P.F., 2014. Ética, sustentabilidade e sociedade da informação e conhecimento. 1st Edition. Lisboa: Chiado Editora.
Anunciação, P.F., 2016. Ethics, etiquette and purpose of life. Retrieved from: https://www.researchgate.net/publication/299856321_Ethics_etiquette_and_purpose_of_life

Toilet4me2 project also considers essential to have an overview of the main ethical aspects that may influence pilot execution, particularly as privacy and data protection are crucial when considering ICT services and platforms that involve older people and vulnerable groups, moreover when concerning intimate contexts as the toilet use. This will impact the economic dimension, especially concerning the system business development. And finally, the societal element, that will receive all the project's benefits.

This approach is fundamental to improve the project's development. The following subchapters will shed light on these ethical challenges, with the relevant background, accessibility, gender and safety concerns, professional conduct principles and informed consent procedures.

3.1 Ethical challenges and background relevant for Toilet For Me

Older people and people with disabilities face many mobility problems due to either bone system degradation or various afflictions that they may suffer from. For this reason, it is necessary to think and develop solutions that improve their quality of life and wellbeing. Assistive living technologies, and guided systems for older adults with physical and cognitive disabilities, might contribute to the reduction of their institutionalization and an improvement of active ageing.[37]

The iToilet project has demonstrated that ICT enhanced physical support can assist people in using a toilet without personal help while safety is preserved. The partners had focused on user autonomy and had an ethical approach due to all project duration.[38]

The Toilet4me project was extremely important and is seen as a background for Toilet4me2 because it made way for both technological and ethical discussion on the development of smart toilets. Some guidelines have already been developed regarding data protection:

- Restricting the access to data based on a "need to know".
- Providing users with unique login data with individual access levels.
- Using encryption when sharing the data.
- Develop a "clean policy," meaning not to leave personal data to unauthorized people.
- Ensuring that all archived data is encrypted.

However, the ethical approach that is proposed in this document goes beyond data protection. This field of research is related to a very sensitive area, in which people often feel ashamed or often see it as a taboo. Given this specificity, the project understands to ethical principles described by the Guidelines for Ethics, Data Privacy and Security AAL[39] to be of

[37] C Balaceanu et al.: Smart Toilet System for Ageing Well, IE 2019 Intern. Conf. on Informatics in Economy, Bucharest, Romania, 30 – 31 May 2019, (paper submitted) Available from: https://www.researchgate.net/publication/335458659_Developing_a_Smart_Toilet_System_for_ageing_people_and_persons_with_disabilities[accessed Aug 12 2020].

[38] Mayer, Peter & Güldenpfennig, Florian & Panek, Paul. (2019). Towards Smart Adaptive Care Toilets. 10.3233/978-1-61499-971-3-9.

[39] AAL Guidelines for Ethics, Data Privacy and Security Available at: http://www.aal-europe.eu/wp-content/uploads/2020/07/AAL-guideliens-for-ethics-final.pdf

great relevance and already presents some recommendations to prevent eventual risks.

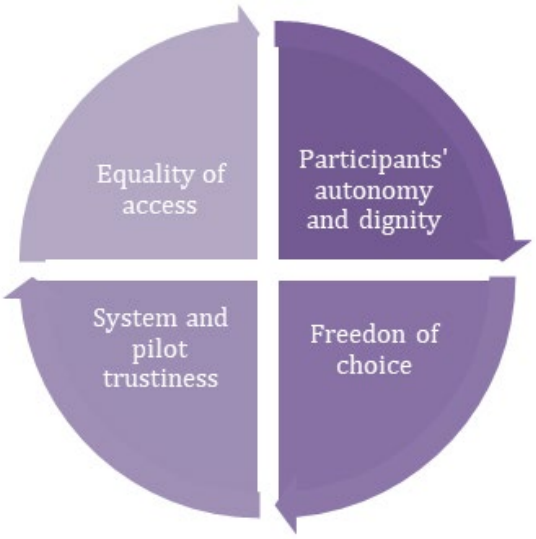


Figure 1: AAL Principles[40]

To put these principles into practice, **it is important for Toilet4me2 to maintain an approach favouring autonomy, aiming to guarantee users dignity**. The researchers' attitude is important in this area. Often, the participants will have difficulty speaking out about their challenges when using the bathroom, so there should be a lot of subtlety and an understanding of the extent to which the users want to expose themselves. In addition, the researcher should facilitate the person's independence as much as their condition allows.

In addition to this care in the day-to-day and when dealing with the user during the pilot phase, researchers and people involved in the research should understand other complexities, such as the difficulty in using and comprehending technologies. Generally, and especially with older adults, there is a lower digital literacy level. It is necessary to make a methodological approach (teach-back method) for the features and system explanation. After the explanation, it is necessary to check if the person really understood and ask to repeat it – without sounding patronizing.

Trust, acceptability and accessibility are the foundation for the technological development and for the pilots. Firstly, the participant must understand the entire project procedure, what the system is about, what are its features, what is the main aim and what are the participant's rights and duties. But, especially, the participants must be sure that their data is protected during all the project. Secondly, the researchers must be sure that new technology brings great benefits but at the same time new risks. Ethical acceptability refers

[40] Figure adapted from the Steering Group of the Support Action on "AAL Guidelines for Ethics, Data Privacy and Security": AAL Guidelines for Ethics, Data Privacy and Security Available at: http://www.aal-europe.eu/wp-content/uploads/2020/07/AAL-guideliens-for-ethics-final.pdf

to a conceptual reflection on the technology that considers the moral issues that emerge from the introduction of new technology: For this reason, it is important to fully explain to the participant all potential benefits from this study, but also go over the risks and how to avoid them as much as possible. Finally, the accessibility approach will be further explained in subchapter 3.2.

These attitudes will reflect and demonstrate the transparency of the project's intentions. **Transparency is about information and embodies honesty and open interaction.** The users must feel safe: physically, financially, and emotionally. All aforementioned international and national legislation determines that participants of scientific studies must have complete knowledge about the objective of the study. **Only then, can the participant's freedom of choice be guaranteed**.

The justice and equality of access will be further developed also in subchapter 3.2.

3.2 Ethical requirements on accessibility, gender and safety

Independent toileting can improve an individual's quality of life through improved hygiene and self-confidence, as well as reduced stigmatism and reduced physical discomforts[41]. Accessibility lies at the core of age-friendly communities and standards can play a key role in facilitating innovation, e.g. through universal design criteria.

Accessibility can be understood as a measure of how a person can participate in an activity[42] and **for sure is more related to the product development, so it is an important aspect to be considered by the technical partners**. Accessibility refers to which a product, device, service, or environment is perceivable, operable, understandable, and robust for use by everyone, including persons with disabilities, or for persons with other special needs or functional limitations.

On the European level, this topic is contained in two EU Directives:

- Directive (EU) 2016/2102, the "Web Accessibility Directive" in force since 22 December 2016, will provide people with disabilities with better access to the websites and mobile apps of public services. The rules laid down in the Directive reflect the Commission's ongoing work to build a social and inclusive European Union, where all Europeans can take a full and active part in the digital economy and society. (EU, 2016)
- Directive (EU) 2019/882, the "European accessibility act", in force since 27 June 2019, is a directive that aims to improve the functioning of the internal market for accessible products and services, by removing barriers created by divergent rules in Member States. (EU, 2019)

A technical reference for ICT products and services (hardware, software, web, digital documents, mobile apps) is the harmonized standard EN 301549 v. 2.1.2.

---

41 Cicero, F. R., & Pfadt, A. (2002). Investigation of a reinforcement-based toilet training procedure for children with autism. Research in Developmental Disabilities, 23(5), 319-331.

42 Acessibility University, 2019. Defining Accessibility. Retrieved from: http://www.accessibleuniversity.com/accessibility-basics/defining-accessibility

In Toilet4me2, accessibility is one of the main targets that must be achieved by the technology to be developed. An inclusive design should considerer different users' needs, in this case, especially in the health area, to create an accessible and affordable product all the while encouraging an active lifestyle.

Also, when developing informative and dissemination documents, the project partners will considerer that it should be accessible by people who live with a form of mobility or cognitive impairment, who are blindvision deaf, , hard of hearing, or have low vision.

Broadly, these are the characteristics of accessible documents:

- Searchable
- Readable

and follow these six Core Skills:

- Headings and document language and structure
- Hyperlinks
- Video captions and audio-descriptions
- Bullets and numbered lists
- Colour contrast
- Image alt-text

Regarding gender aspects, the consortium will follow the principles for guaranteeing responsible innovation, taking into account ethics, no discrimination and public engagement. The project will consider positive discrimination to promote e-inclusion, safeguarding gender equality and seeking to ensure gender equality in all aspects of the project and throughout the project's lifecycle. Gender equality is based on equal treatment and opportunities as defined by the European and UN Policies (e.g. Council Directive 75/117/EEC[43]) and is adapted by the members of this consortium.

Some specifics issues arise when it is thought about ICT tools in the socio-sanitary context and related to the gender context. Usually, men have more difficulties to talk about toilet problems. This is related with a desire to be autonomous for more time. The women usually talk about these issues and seek strategies to solve the problems. This self-care is often a women's characteristic, also because care in general is associated with being a woman.

These and many other general characteristics that consider gender issues will be measured by the project, especially when dealing directly with participants. Furthermore, in the development of technology, both genders necessities should be taken into consideration since they have distinct characteristics and requirements.

Another important aspect is safety. Independent living brings several challenges, some connected to safety. Falls are among the most common accidents involving older people and persons with disabilities. In this case, the project will try to mitigate the risk of falls and prevent another kind of risks involving the users. One of the measures that Toilet4me2 will have transversally throughout the project is the collection of good practices and materials

[43] https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31975L0117

connected to safety, that will then be distributed to all concerned partners and, when applicable or wished, adapted and translated to the different pilot sites.

3.3 Professional conduct principles in the design and implementation of ICT tools in the socio-sanitary context

A growing number of older people, people with disabilities and a rise in the numbers of obesity entails the need for products and services specifically developed, which can provide a better quality of life, by fulfilling their most basics need. The socio-sanitary context is an example and, in most situations, is forgotten by the ICT tools developers. Considering this, Toilet4me2 aimed to give an answer and improve the wellbeing of these vulnerable persons.

Following the "Design for all" and co-creation approaches, the project ensures that users' needs are fully addressed when it comes to the development of products and environments. Design for all aims to address the needs of currently marginalised and under-represented groups who are left out of the mainstream design practices. Thereby assuring a direct link to the concept of an inclusive society. This design for all entails a close interaction with the users, working together towards innovation and new product development[44] This joint work can help engineers and developers to identify relevant issues regarding that topic and address them whilst developing the product[45].

Design for all in the Toilet Environment can be considered a sensitive topic of research, as participants can feel uncomfortable or embarrassed talking about their personal hygiene and toileting. To obtain useful data, the researchers must ensure the users feel comfortable and safe during the trials.[46]

In addition to this main approach, some principles arising from legislation, especially from the GDPR, should be observed from the beginning of the development of the system.

- Follow a user-centred design approach and an agile development
- Internal policies, such as employee confidentiality agreements, secured storage of documents containing personal data, internal trainings on information security management and intellectual property protection, controlled password-protected access to personal computers and to databases containing personal data, privacy by design techniques and encrypted file transfers.
- Adequate service models and care protocols
- Implement remote monitoring success factors, e.g. friendly user interfaces, good analytic procedures, education and coaching actions and devices with good quality

[44] http://designforall.org/design.php. Internet: 21 August 2020.

[45] P. Panek, G. Fazekas, T. Lueftenegger, P. Mayer, T. Pilissy, M. Raffaelli, A. Rist, R. Rosenthal, A. Savanovic, A. Sobjak, F. Sonntag, A. Toth, B. Unger (2017) On the Prototyping of an ICT-Enhanced Toilet System for Assisting Older Persons Living Independently and Safely at Home, in: D. Hayn and G. Schreier (Eds.) Health Informatics Meets eHealth, Proc of the 11th eHealth2017 Conf, 23-24 May 2017, Vienna, Austria, Studies in Health Technology and Informatics, Vol. 236, IOS press, DOI 10.3233/978-1-61499-759-7-176, pp. 176 – 183. [PDF (open access)]

[46] When Ethical Guidance Is Missing and Do- It-Yourself Is Required: The Shaping of Ethical Peer Review and Guidance in the FRR Project.

- The security analysis should address requirements for confidentiality, data integrity, availability and accountability.
- An authorization model should be defined so that any access to identifiable personal data is strictly controlled.
- The users should be informed of what kinds of information are being recorded, and for what purposes.
- Back-ups of participants data, secure server host environment with safeguards and firewall protection; regular system check-ups

3.4 Informed consent procedures and templates

This subchapter aims to present in a structured way the procedures that the pilot's partners must follow to inform the participants correctly at the time of recruitment. Before the interview or test starts, the persons involved must be informed about the type of monitoring and recording instruments that will be applied. For this reason, the project has developed an informed consent template, to reassure that the information is strengthened and clearer for the persons involved.

So, putting into practice some EU guidelines, the partners involved in the pilot must be aware that:

- All the collected data must be fully understood and accepted by the person involved, guarantying the voluntary basis. For this reason, the partners should use short and easy terms and conditions. (EU, 2016)
- A full explanation may be required to guarantee that the person has complete acknowledge of the data involved and agrees with this collection.
- The information supplied to the person must address eventual risks and possible difficulties and researchers must not be hesitant in doing this as clearly as possible. (EU, 2016).
- The regulation still determines that the data and relevant part of any recordings must be deleted or destroyed if the test subject requests. (EU, 2016)

It is important to highlight that, end-users who are unable to give informed consent will not be asked to participate (this is part of the exclusion criteria). Participation is voluntary and end-users can leave the study at any time for any reason if they wish to do so, without any consequences.

When older adults are involved in projects, the pilots' researchers should implement their ethical concerns, aiming to achieve balance between all documentation required for research and ethics clearance purposes and the adequacy of language that is necessary to obtain proper and freely given informed consent. In many cases, involving family members or professional caregivers is necessary for best pilot organization, so co-operation and trust is key.

The Informed Consent package (available in D3.1. See attachment for more details) was based on international best practices. The Template for Clinical Studies provided by the World Health Organization Research Ethics Review Committee (WHO, ERC) is a good illustration and served as guidance.

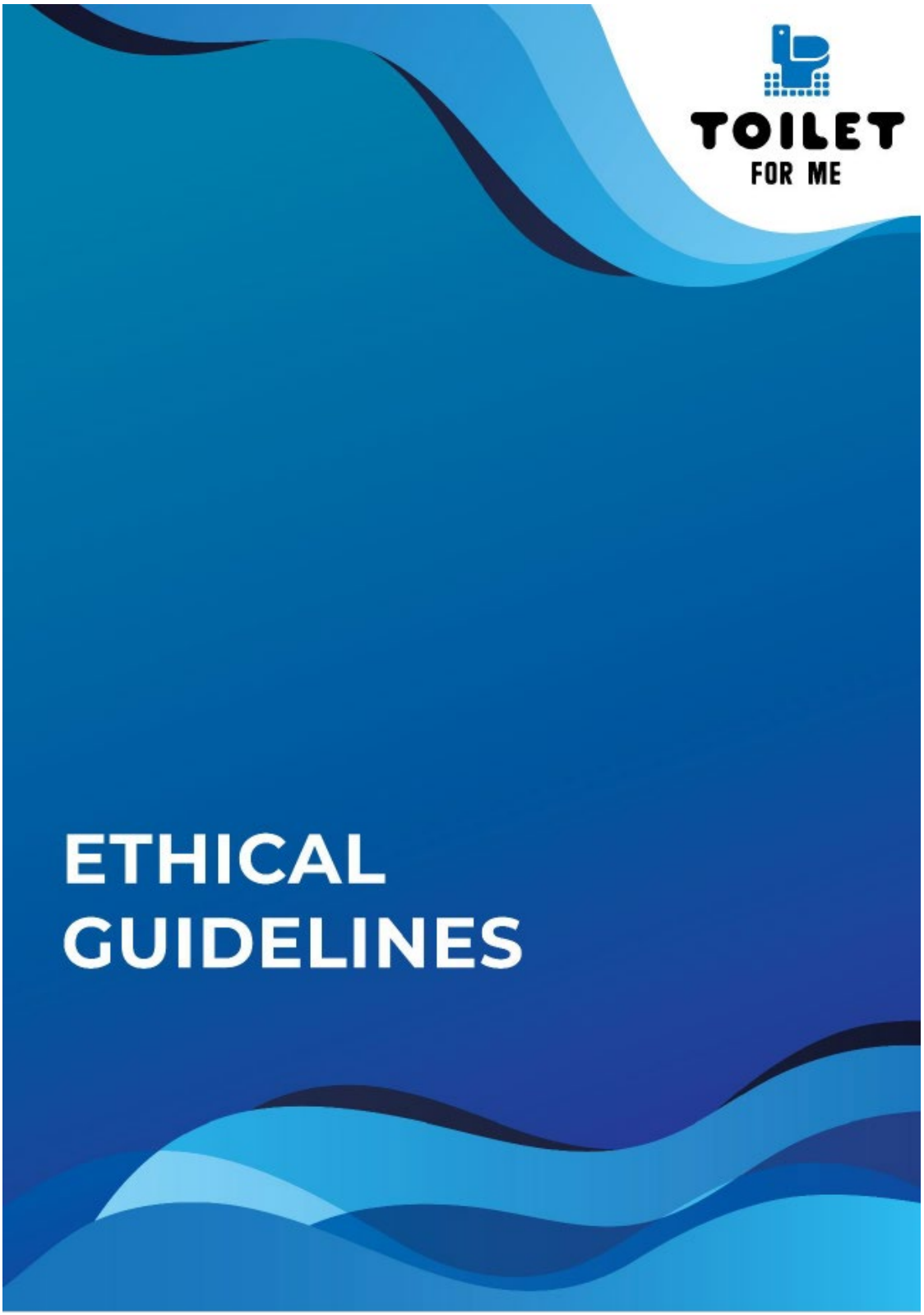
Participants that are to be recruited for the Toilet4me2 pilots, will thus receive a written package (cf. Annex 5) containing the following elements:

- Factsheet: template factsheet to be delivered to the participant and those involved in the project. It describes the main contacts from each pilot site, the project background, its t facts and objectives, social media links and partners logos. Each factsheet was then translated to national languages and adapted / tailored to the needs of each country and their relevant contacts.
- IC template: The informed consent template contains detailed information about the study.
- Revocation form: A form to be filled in by any participant who wishes to abandon the project.

3.5 Ethics Committee

Representatives of all end-user groups will be involved in an Ethics Board that will assess adequacy and easy understanding of all materials and support the supervision of all Ethical issues raised during the project. The Ethics Board regulation is described in the annex 7.3.

4 Guidelines




THE GUIDELINES
REFLECTIONS
• National specificities on law and regulations.
• Professional ethics and deontology.
• Particularities to require the national ethical approval.
• User/ participant needs and wills.
• Data sharing governance. GDPR is the principal source.
GENERAL MEASURES
• Co-creation.
• Accessibility.
• Gender equality.
• User safety first. Special attention to the vulnerable ones.
• GDPR.
• Informed Consent.
PILOT SITE ACTIONS
• Compliance with European and National Laws.
• Respect for the individual.
• Apply the Informed consent procedures.
• Attention to the right of privacy.
• Observe data minimisation
GUIDELINES TO TECH PARTNERS
• Compliance with the ethical guidelines (legal behaviour is not enough)
• Set human lives behind tech.
• Consider users expectations.
• Apply Privacy and Security by Design principle.
• Monitor additional risks for technological.
• Implementation of Crisis simulations
• Observe data protection measures:
- Access control
- Integrity
- Pseudonymisation
- Encryption
- Transmission control
- Confidentiality
- Recoverability
ORGANISATIONAL MEASURES
• Reflection about Ethics guidelines.
• Implementation of Ethics Board.
• Observance of ethical leadership during all project.
• Apply Privacy and security by design principle.
• Share the knowledge and issues between the partners.

THE TOOLS

To guarantee that all end-users are protected, namely the most vulnerable ones, see the measures you should follow:

ETHICAL SUMMARY

Researchers, technical partners, and end-users organizations must protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information from the users/participants.

Participants 'rights and interests cannot be left aside as they are more important than the research itself.

The recognition of the increased vulnerability of individuals and groups calls demands for special vigilance and protection.

The trust, acceptability and accessibility are the foundation for the technological development and for the pilots.

The end-user right of information must be observed. The informed consent should bring all data regarding the project and the pilot – all the participants' rights and duties.

The collection of personal data must be conducted in a fair manner. The informed consent and the scientific plan must indicate the purposes for the data collected and the researchers must ensure that appropriate security of the personal data, including protection against unauthorized or unlawful.

Data controllers must be able to demonstrate they are GDPR compliant.

TOOLS FOR ETHICAL COMPLIANCE

5 Definitions, Acronyms and Abbreviations

AAL	Active and Assisted Living / Ambient Assisted Living
BEIA	BEIA Consult International, partner in T4ME2 project
CCS	CareCenter Software GmbH, partner in T4ME2 project
CA	Consortium Agreement
CDC	Caritas de Coimbra, subcontractor of OSF
CMU	Central Management Unit
COG	cogvis software & consulting GmbH, partner in T4ME2 project
DoW	Description of Work, proposal, work descriptoin of T4ME2 project
GD	Stichting Gouden Dagen, partner in T4ME2 project
GDPR	EU General Data Protection Regulation (GDPR)
HH	Zorggroep Heilig Hart, partner in T4ME2 project
ICT	Information and Communications Technologies
iToilet	previous AAL project iToilet (supportive ICT enhanced toilet for the home market, http://www.itoilet-project.eu/)
OSF	On Site Foundation, partner in T4ME2 project
PU	Primary Users (e.g. old person, person with physical limitation)
PrM	Project Month. Starting month is PrM01 i.e. March 2020
SAN	Sanmedi bv, partner in T4ME2 project
STR	Sanitronics International B.V., partner in T4ME2 project
SIS	Santis Kft, partner in T4ME2 projec, partner in T4ME2 project
SU	Secondary Users (e.g. care person)
Toilet4me2, T4ME2	Toilet for me too, supporting active living in (semi-) public environments by suitable toilets (AAL project at hand, website: http://toiletforme.com/)
Toilet4me	previous AAL project Toilet4me (was a SCP as preparation for T4ME2 for semi-public area, http://toilet4me-project.eu/)
TU	Tertiary Users (e.g. manager of day care organisation)
TUW	TU Wien (Vienna Univ. of Technology), partner and co-ordinator in T4ME2 project
WP	Work Package

6 Literature

AAL Guidelines for Ethics, Data Privacy and Security Available at: http://www.aal-europe.eu/wp-content/uploads/2020/07/AAL-guideliens-for-ethics-final.pdf

Accessibility University, 2019. Defining Accessibility. Retrieved from: http://www.accessibleuniversity.com/accessibility-basics/defining-accessibility

Anunciação, P.F., 2014. Ética, sustentabilidade e sociedade da informação e conhecimento. 1st Edition. Lisboa: Chiado Editora.

Anunciação, P.F., 2016. Ethics, etiquette and purpose of life. Retrieved from: https://www.researchgate.net/publication/299856321_Ethics_etiquette_and_purpose_of_life

C Balaceanu et al.: Smart Toilet System for Ageing Well, IE 2019 Intern. Conf. on Informatics in Economy, Bucharest, Romania, 30 – 31 May 2019, (paper submitted) Available from: https://www.researchgate.net/publication/335458659_Developing_a_Smart_Toilet_System_for_ageing_people_and_persons_with_disabilities[accessed Aug 12 2020].

Cicero, F. R., & Pfadt, A. (2002). Investigation of a reinforcement-based toilet training procedure for children with autism. Research in Developmental Disabilities, 23(5), 319-331.

Council of Europe (COE), 1950. Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocols No. 11 and No. 14. Retrieved from: https://rm.coe.int/1680063765

Council of Europe (COE), 1981. Convention 108: Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Retrieved from: https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/108

Council of Europe (COE), 1981. Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Retrieved from: https://rm.coe.int/1680078b37

European Center for Constitutional and Human Rights. Glossary. Hard Law / Soft Law. Available at: https://www.ecchr.eu/en/glossary/hard-law-soft-law/

European Commission (EC), 2007. Opinion 4/2007 on the concept of personal data. Retrieved from: https://www.gpdp.gov.mo/uploadfile/others/wp136_en.pdf.

European Union (EU), 1992. Treaty on European Union. Retrieved from: https://europa.eu/european-union/sites/europaeu/files/docs/body/treaty_on_european_union_en.pdf

European Union (EU), 1997. Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31997L0066

European Union (EU), 1999. Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31999L0005

European Union (EU), 2002. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications). Retrieved from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32002L0058

European Union (EU), 2006. Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC. Retrieved from: https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32006L0024

European Union (EU), 2012. European Group on Ethics in Science and New Technologies (EGE) Retrieved from: https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/ege_en

European Union (EU), 2016. Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016L0680

General Data Protection Regulation (GDPR), 2018. General Data Protection Regulation. Retrieved from: https://gdpr-info.eu/

Mayer, Peter & Güldenpfennig, Florian & Panek, Paul. (2019). Towards Smart Adaptive Care Toilets. 10.3233/978-1-61499-971-3-9.

P. Panek, G. Fazekas, T. Lueftenegger, P. Mayer, T. Pilissy, M. Raffaelli, A. Rist, R. Rosenthal,

A. Savanovic, A. Sobjak, F. Sonntag, A. Toth, B. Unger (2017) On the Prototyping of an ICT-Enhanced Toilet System for Assisting Older Persons Living Independently and Safely at Home, in: D. Hayn and G. Schreier (Eds.) Health Informatics Meets eHealth, Proc of the 11th eHealth2017 Conf, 23-24 May 2017, Vienna, Austria, Studies in Health Technology and Informatics, Vol. 236, IOS press, DOI 10.3233/978-1-61499-759-7-176, pp. 176 – 183. [PDF (open access)]

United Nations Educational, Scientific and Cultural Organization (UNESCO), 2005. Universal Declaration on Bioethics and Human Rights. Retrieved from: https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights

When Ethical Guidance Is Missing and Do- It-Yourself Is Required: The Shaping of Ethical Peer Review and Guidance in the FRR Project. Available at: https://www.researchgate.net/publication/290594668_When_ethical_guidance_is_missing_and_do-it-yourself_is_required_The_shaping_of_ethical_peer_review_guidance_in_the_FRR_project

World Medical Association. WMA Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Other sites:

http://www.monitorpolski.gov.pl/mp/2018/1169/M2018000116901.pdf

http://designforall.org/design.php.

http://www.cdep.ro/pdfs/reviz_constitutie_en.pdf

http://www.ceom-ecmo.eu/sites/default/files/documents/romanian_code_of_medical_deontologypdf.pdf

http://www.dutchcivillaw.com/

http://www.en.pollub.pl/files/17/attachment/96_The-Act-of,Personal,Data,Protection,1997.pdf

http://www.eurecnet.org/information/poland.html

https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31975L0117

https://not.org.pl/

https://www.bmia.be/en/home/

https://www.ccbe.eu/NTCdocument/en_poland_law_on_adv1_1188889310.pdf

https://www.ivir.nl/syscontent/pdfs/145.pdf

https://www.kuleuven.be/english/research/integrity/practices/belspo-code

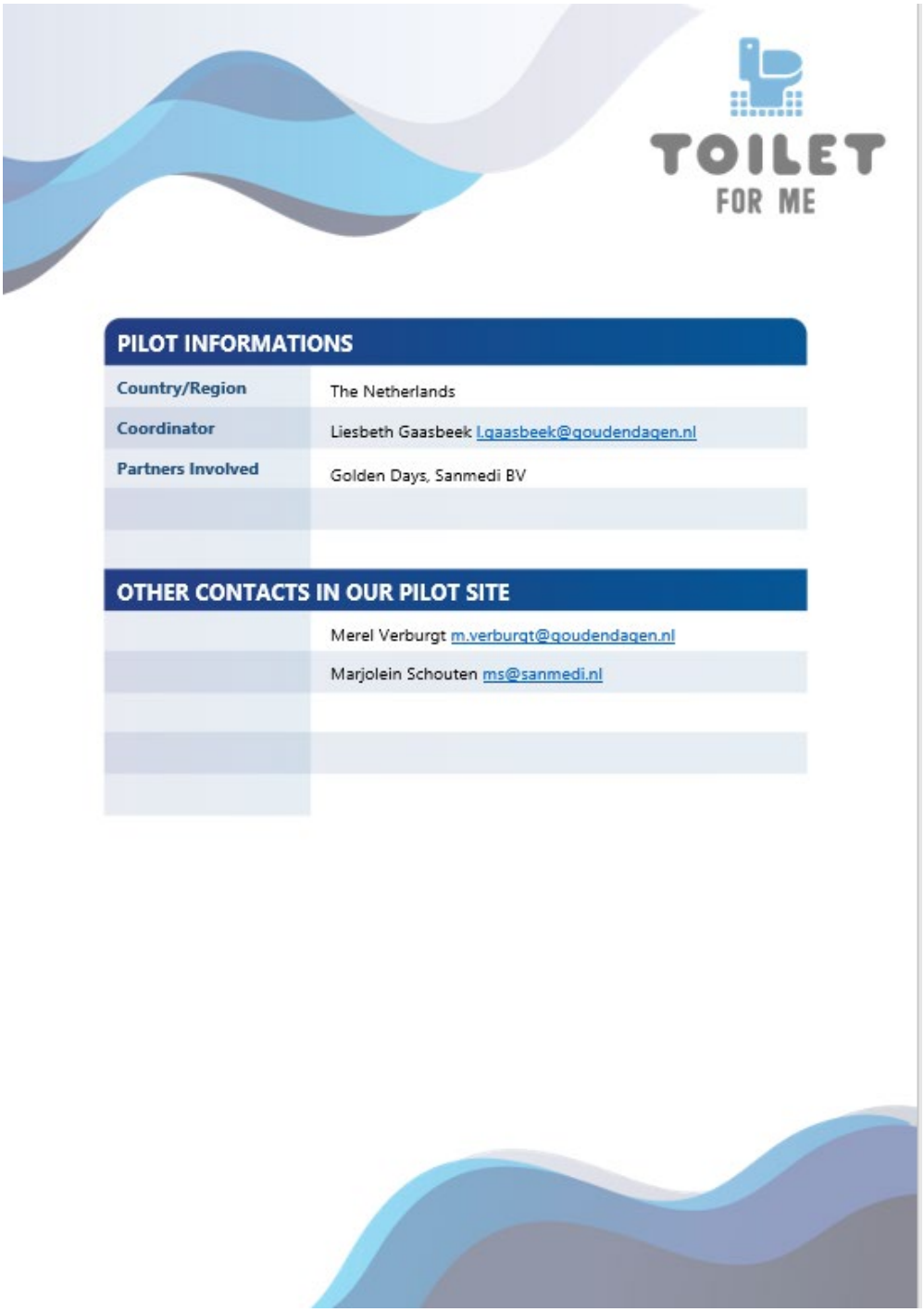
https://www.nyulawglobal.org/globalex/Romania1.html#_5.4_Civil_law

https://www.vsnu.nl/files/documents/Netherlands%20Code%20of%20Conduct%20for%20Research%20Integrity%202018.pdf

7 Annex

7.1 Informed consent pack

7.1.1 FACT SHEET – Dutch partner



TOILET FOR ME

PILOT INFORMATIONS	
Country/Region	The Netherlands
Coordinator	Liesbeth Gaasbeek l.gaasbeek@goudendagen.nl
Partners Involved	Golden Days, Sanmedi BV

OTHER CONTACTS IN OUR PILOT SITE	
	Merel Verburgt m.verburgt@goudendagen.nl
	Marjolein Schouten ms@sanmedi.nl

PROJECT BACKGROUND

Current assistive sanitary components for the private home area do not meet the usability requirements of public high frequency multi-user environments, are not seamlessly integrated and lack required robustness and design.

The area of personal hygiene and toilet use is an important area in daily life which unfortunately has not yet found much interest in the AAL community. Despite a high need for individualised and well-tailored support, not much AAL technology is available in the bathroom and up till now only a few research projects (mostly from members of the T4ME2 consortium) have addressed this topic.

Offering the support in places which older persons frequently visit or would like to visit (but currently are unable to do due to lack of suitable toilet facilities) will allow people to participate in society more, which will contribute to their independence and quality of life.

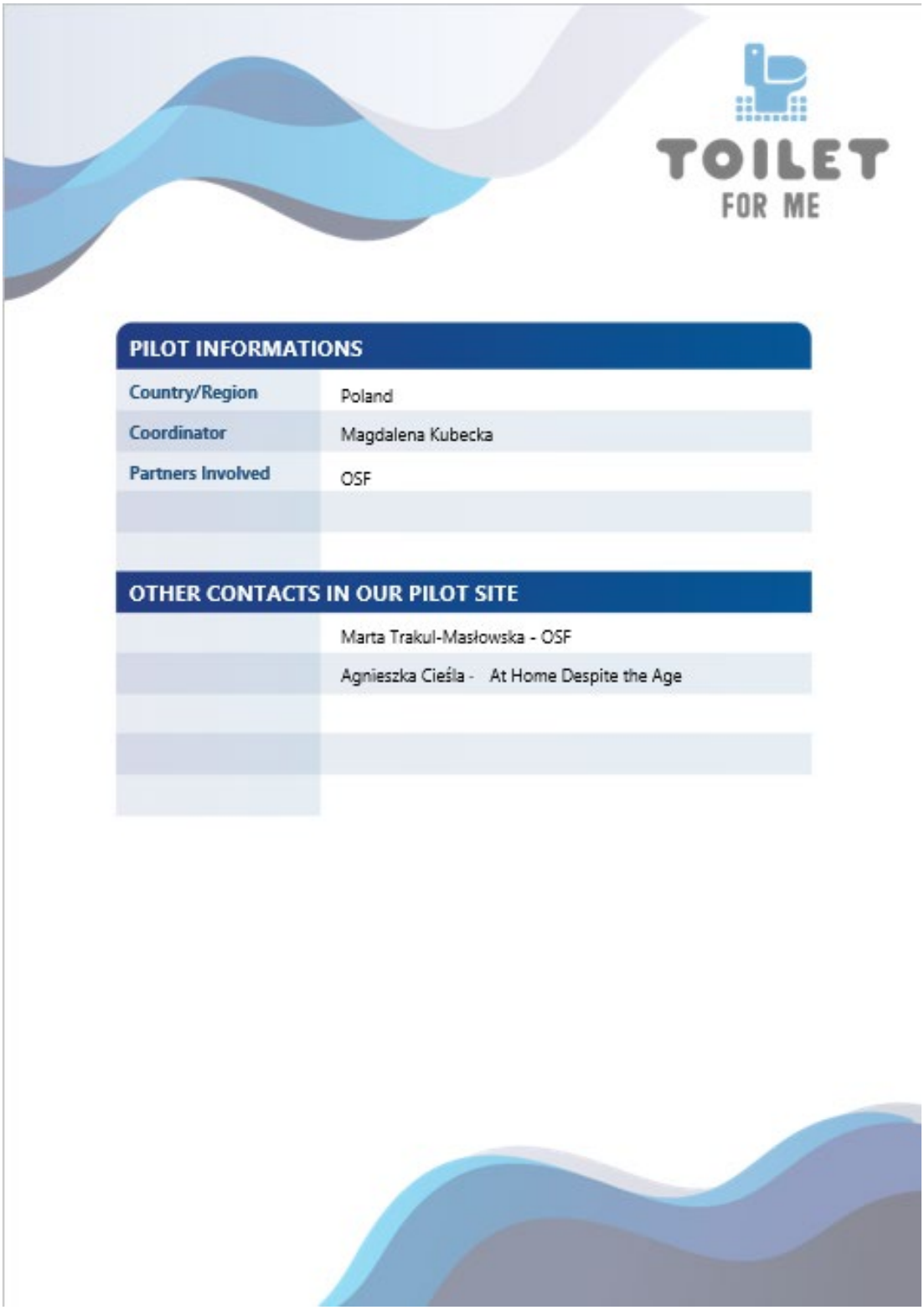
One of the things that prevents disabled and elderly people from going out is going to the toilet.

PROJECT OBJECTIVES

The project provides supportive, autonomy promoting, smart toilet solutions for living-well. It addresses ageing people and persons of all ages with impairments/disabilities (as well as their (in)formal caregivers) and their needs when using a toilet outside home in public or semipublic environments.
It will empower and support more persons to go outdoors and to actively participate in the society without need for personal support on the toilet. Additionally it will bring up new market areas with important customers, e.g. for hotels offering state-of-the-art accessible and adaptable hotel rooms as USP in accessible tourism.
It will prepare the transfer to an open innovation product for commercialisation by establishing demonstration sites at the user partners based on redesigned, integrated, accessible and flexible, certifiable, nonstigmatising and robust prototype solutions with ICT interfaces for personalisation and safety.

toiletforme.com info@toilet4me-project.eu

7.1.2 FACT SHEET – Polish partner



TOILET FOR ME

PILOT INFORMATIONS	
Country/Region	Poland
Coordinator	Magdalena Kubecka
Partners Involved	OSF

OTHER CONTACTS IN OUR PILOT SITE	
	Marta Trakul-Masłowska - OSF
	Agnieszka Cieśla - At Home Despite the Age

PROJECT BACKGROUND

Current assistive sanitary components for the private home area do not meet the usability requirements of public high frequency multi-user environments, are not seamlessly integrated and lack required robustness and design.

The area of personal hygiene and toilet use is an important area in daily life which unfortunately has not yet found much interest in the AAL community. Despite a high need for individualised and well-tailored support, not much AAL technology is available in the bathroom and up till now only a few research projects (mostly from members of the T4ME2 consortium) have addressed this topic.

Offering the support in places which older persons frequently visit or would like to visit (but currently are unable to do due to lack of suitable toilet facilities) will allow people to participate in society more, which will contribute to their independence and quality of life.

PROJECT OBJECTIVES

The project provides supportive, autonomy promoting, smart toilet solutions for living-well. It addresses ageing people and persons of all ages with impairments/disabilities (as well as their (in)formal caregivers) and their needs when using a toilet outside home in public or semi-public environments.
It will empower and support more persons to go outdoors and to actively participate in the society without need for personal support on the toilet. Additionally, it will bring up new market areas with important customers, e.g. for hotels offering state-of-the-art accessible and adaptable hotel rooms as USP in accessible tourism.
It will prepare the transfer to an open innovation product for commercialisation by establishing demonstration sites at the user partners based on redesigned, integrated, accessible and flexible, certifiable, no stigmatising and robust prototype solutions with ICT interfaces for personalisation and safety.

toiletforme.eu @– fb.com/ @–

7.1.3 FACT SHEET – Romanian partner

TOILET FOR ME

PILOT INFORMATIONS	
Country/Region	Romania
Coordinator	George Suciu
Partners Involved	BEIA

OTHER CONTACTS IN OUR PILOT SITE	
	Cristina Balaceanu - BEIA
	cristina.balaceanu@beia.ro

PROJECT BACKGROUND

Current assistive sanitary components for the private home area do not meet the usability requirements of public high frequency multi-user environments, are not seamlessly integrated and lack required robustness and design.

The area of personal hygiene and toilet use is an important area in daily life which unfortunately has not yet found much interest in the AAL community. Despite a high need for individualised and well-tailored support, not much AAL technology is available in the bathroom and up till now only a few research projects (mostly from members of the T4ME2 consortium) have addressed this topic.

Offering the support in places which older persons frequently visit or would like to visit (but currently are unable to do due to lack of suitable toilet facilities) will allow people to participate in society more, which will contribute to their independence and quality of life.

PROJECT OBJECTIVES

The project provides supportive, autonomy promoting, smart toilet solutions for living-well. It addresses ageing people and persons of all ages with impairments/disabilities (as well as their (in)formal caregivers) and their needs when using a toilet outside home in public or semipublic environments.
It will empower and support more persons to go outdoors and to actively participate in the society without need for personal support on the toilet. Additionally, it will bring up new market areas with important customers, e.g. for hotels offering state-of-the-art accessible and adaptable hotel rooms as USP in accessible tourism.
It will prepare the transfer to an open innovation product for commercialisation by establishing demonstration sites at the user partners based on redesigned, integrated, accessible and flexible, certifiable, nonstigmatising and robust prototype solutions with ICT interfaces for personalisation and safety.

7.1.4 FACT SHEET – Belgium partner

TOILET FOR ME

PILOT INFORMATIONS	
Country/Region	Belgium
Coordinator	Dave Dewachtere: dave.dewachtere@h-hart.be
Partners Involved	H-Hart

OTHER CONTACTS IN OUR PILOT SITE	
	Justine Asselman justine.asselman@h-hart.be
	Arend Roos : ar@arendroos.nl

PROJECT BACKGROUND

Current assistive sanitary components for the private home area do not meet the usability requirements of public high frequency multi-user environments, are not seamlessly integrated and lack required robustness and design.

The area of personal hygiene and toilet use is an important area in daily life which unfortunately has not yet found much interest in the AAL community. Despite a high need for individualised and well-tailored support, not much AAL technology is available in the bathroom and up till now only a few research projects (mostly from members of the T4ME2 consortium) have addressed this topic.

Offering the support in places which older persons frequently visit or would like to visit (but currently are unable to do due to lack of suitable toilet facilities) will allow people to participate in society more, which will contribute to their independence and quality of life.

One of the things that prevents disabled and elderly people from going out is going to the toilet.

PROJECT OBJECTIVES

The project provides supportive, autonomy promoting, smart toilet solutions for living-well. It addresses ageing people and persons of all ages with impairments/disabilities (as well as their (in)formal caregivers) and their needs when using a toilet outside home in public or semipublic environments.
It will empower and support more persons to go outdoors and to actively participate in the society without need for personal support on the toilet. Additionally it will bring up new market areas with important customers, e.g. for hotels offering state-of-the-art accessible and adaptable hotel rooms as USP in accessible tourism.
It will prepare the transfer to an open innovation product for commercialisation by establishing demonstration sites at the user partners based on redesigned, integrated, accessible and flexible, certifiable, nonstigmatising and robust prototype solutions with ICT interfaces for personalisation and safety.

toiletforme.com info@toilet4me-project.eu

7.2 Informed Consent Form (draft proposal)

Informed consent forms [draft proposal]
Information folder for participation in the project Toilet4me2
[Evaluation study]

Dear Sir / Madam,
You have been invited to take part in this evaluation study which is part of a European research project whose main objective is [describe project objectives]. You will receive detailed information about this study in a personalized way.

This information folder has two parts:
- Part I: General information about the study
- Part II: Informed Consent [to be signed if you agree to participate in the study]
- Part III: Revocation of Consent [to be used only in case the participant wish to leave the study]

If you do not want to participate, this will not affect your relationship with the institution in any way, and there will be no negative consequences for you. If you agree to participate, you are also free to leave the study at any time. Your choices and your rights will always be respected.

The engagement of people in research projects is essential to deliver useful and relevant results. So, we need you to provide your written consent to cooperate with us. Please carefully read the Part I of this information folder before making a decision. You can also ask for the clarifications you need and ask any question that does not have a clear and complete answer in this document.

Sign Part II of the information folder only if:
- You fully understood the type and procedure of the evaluation study.
- You are willing to give your consent in writing.
- You understand your rights as a participant in this research project.

PART I: GENERAL INFORMATION.

1. What is the purpose of this evaluation study?
The evaluation study is part of the activities of the research project – [describe project contracts, programs].
The overall objective of the Toilet4me2 project is [describe project objectives]. The project will utilise [describe the technology in a simple way].
Toilet4me2 will be validated [describe pilots]
The purpose of this evaluation study is to:
i. [FILL describe purposes here]

2. Who is the responsible for the study in [FILL pilot site]?
The project has the participation of [FILL Institution name].
[FILL Institution name] is responsible for the activities in [FILL pilot site].
Responsible for the study at [FILL *Institution name*] and its data processing:
Principal Investigator responsible for the study at [*Institution name*]
Name – [FILL]
Contacts – [FILL telephone number | [email]

3. How will this evaluation study work?
This evaluation study of the Toilet4me2 project will take place at the [FILL pilot sites].
A total of [FILL end-users number involved in this pilot site; end-users number involved in the others pilot sites]. Inclusion criteria are: [FILL].The trial will last for [FILL].
You will be provided by the following equipment: [FILL]
The technical partners will provide technical support whenever you need. During the trials you [FILL participant role in the trial].
During the trial you will fill in several questionnaires to evaluate your findings. In between you always can provide the researchers and technical partners with informal feedback and comments.
The questionnaires will collect general data about you, namely [FILL with questions]. These questionnaires will help us evaluate the issues related to [FILL what questionnaires will evaluate], so that you can evaluate the benefits that the Toilet4me2 Project can have in your life.
Questionnaires and interviews are not intended to collect personal information or test your personal abilities. Your contribution is of utmost importance to improve the system, so that it becomes even more useful and accessible to the needs of older people.

4. What are the benefits of your participation in the study?
By participating in this study, by providing your opinions, you are contributing to the development of a services system that supports [describe system benefits]. This services system aims to [describe system objectives].
The results of this evaluation trial allow us to evaluate whether Toilet4me2 is useful for you and other older adults [describe other end-users].

5. Are there any risks, discomforts or side effects related to your participation in this study?
[describe any risks to participants that may arise during the pilot]

However, if you find any doubt, difficulty or problem, immediately contact the responsible investigator for the study in [*describe pilot sites*].

6. Is there any cost of participating in the study? Is there any financial reimbursement for participants?

Absolutely no costs or any other consequences will arise for you as a participant of this study. The participant will also not receive any financial compensation for participating in the study.

In the event of any accidental damage of the technical equipment during the study period, the Toilet4me2 support system will be repaired or replaced by the study team members. If you wish to continue using the Toilet4me2 system after the end of the study, because it has brought personal benefits that you do not want to lose, please inform a member of the study team. Without any commitment at this time, we will try to find a solution.

7. Data Protection

In what way will the collected data of this evaluation trial be used?

All data will be protected against unauthorised access. The data collected about you will be safely stored by [*FILL*]. The data will be transferred for analysis to the [*FILL – with the place/entity where data will be analysed*] after the [*FILL anonymization?, pseudo anonymization?*]. This means that [FILL e. g. your name will be replaced by a number and only the person in charge of the data processing from [institution] will be able to make the link between your number and your name. In addition, those responsible for the study will not have access to your date of birth (only your age) and your address will be registered only at the institution. In this way, it will not be possible for any other researcher to identify what were your responses.

The pseudo-anonymised data are only shared with other institutions of the consortium of the project. If the data is shared with other researchers and research institutions that are not part of the consortium the data will be completely anonymous, and your name and address will never be included and cannot be identified. Likewise, any publications that may result from this study will not include any personal data that may lead to your identification.

You can oppose your consent to the processing of your data at any time. After this decision no further data will be processed. Data already collected until your withdrawal may be included in the study, unless you expressly wish to exclude it.

You may also have access to all of the data collected during the study and make corrections if you find any misunderstanding.

Your participation is planned to last [FILL]. The research team involved in this study ensures that the resulting material will be stored in a safe, anonymized location no later than [FILL] years after the completion of the study. All members of this study are bound by European data protection standards.

If you have any questions about the processing of your personal data, please contact the person in charge of data processing of this institution.

8. Early withdrawal of your participation in the study

You can interrupt your participation at any time without any explanation. The withdrawal will have absolutely no negative consequences for you at [FILL institution].

Even after completing the study, you have the right to express your wish that your data

be removed and deleted, except for those that have already been published or used in reports that cannot be redeemed or changed. To request the deletion of your data, please contact the investigator in charge of the project.
To interrupt your participation in the project or request the deletion of your data, please contact the project manager, by phone or email. You can find the contacts at the end of this document.

9. Possibility to discuss other issues
If you have any questions about the project or about your participation in it, you can contact the project manager at [FILL institution] (see contact details below) now or later.
You can also contact the partner entity of the project, responsible for the study at international level – [FILL name, institution, place, email address]. In addition to the responsible researcher for the study and the person in charge of data processing of [pilot sites], you have the right to complain to the [FILL country] National Data Protection Commission about the processing of your personal data through [FILL e-mail, telephone].

10. Contacts
Responsible for the study at [FILL institution] and its data processing
Principal Investigator responsible for the study at [*Institution name*]
Name – [FILL]
Contacts – [FILL telefone number | [email]
Data Protection Officer at *Institution name*]
Name – [FILL]
Contacts – [FILL telefone number | [email]
Responsible researcher at international level
Name - [FILL name, institution, place, email address, telephone]

If you wish to participate in this study Toilet4me2, we would like you to complete Part II – Informed Consent Statement and to keep this information folder.

PART II: INFORMED CONSENT STATEMENT

I have been thoroughly and comprehensively informed about the objective, the meaning and the scope of Toilet4me2 evaluation trial and any resulting requirements as well as all potential risks and possible impacts on my home and my life. This information was given by Mr /Mrs _____.
I have read the above [FILL] pages of information, (or it has been read to me). I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. As a consequence, I am able to confirm that I have understood the provided information.
I will adhere to any requirements that are necessary for the implementation of the evaluation trial while reserving the right to withdraw my voluntary participation at any given time with no negative consequences to my person.

I consent voluntarily to participate in this research project:

- I declare my consent to take part in this evaluation trial.
- I declare my consent to recording (including interview voice recording and transcription), transfer and storage of my personal data as described in chapter 7: Data protection.
- I declare my consent to the sharing of my personal data between the Toilet4me2 project partners for the benefit of this project according to national laws.
- I declare my consent to the sharing of completely anonymized data (can never be traced back to your person) with organizations outside the Toilet4me2 project and for an unlimited period of time.

Name of the participant: _____
ID number: _____
Identification Code: _____

I have received a copy of this patient participation informed consent form. The original form will be stored at the care service provider.

Signature of participant: _____
Day/month/year: _____

Data protection of participants
By signing this form, I agree with the processing of my personal data and its anonymous transmission possibly also outside the European Union, for research purposes.

Signature of the participant: _____
Date: ____ /____ /____

TO BE COMPLETED BY THE RESPONSIBLE OF THE STUDY IN THIS ORGANISATION

I, _____ declare that the participant spontaneously signed and agreed to his participation in this study.

I also declare that:

- I provided the participant with all the necessary information for the understanding of this study, its purposes, procedures, possible risks and benefits.
- I confirmed that the participant understood the provided information.
- I provided time for reflection and the opportunity to ask questions about the study.
- I have not exercised any coercion or otherwise influenced his/her consent.

Signature: _____

Date: ____ /____ /____

PART III: REVOCATION OF CONSENT
(To be used only in case you wish to leave the Toilet4me2 study)

Dear Sir / Madam,

You have been invited to take part in the Toilet4me2 study, which is part of a European research project with the main objective of [describe project objectives]

However, you withhold the right to interrupt your participation at any time, without having to provide particular explanation, and not being subject to any negative associated consequences for you at _____ [FILL institution]. In case you intend to exercise that right, please fill with your data below, if possible, in your own handwriting.

I, Mr/Mrs [strike out what does not apply] ….……, with the ID number ……, REVOKE the consent previously given for the inclusion of my data in the Toilet4me2 research study, without having received any kind of opposition or undesirable consequences.

_____, _____ of _____ of 20____.
[INSERT location and date]

The participant: _____
[If possible, please sign in your own handwriting]

7.3 Ethics Board Regulation

TOILET4ME2 PROJECT ETHICS BOARD

Article 1 (Object)

This Regulation establishes the form of action and rules of Toilet4me2 Ethics Board (EB).

Article 2 (Definition)

The EB is a collegiate body, established within Toilet4me2 project that aims to ensure that this project will obey to ethical and deontological principles in research with humans, processing and protection of sensitive personal data. It will further ensure that the perspectives, values and needs of persons involved in the pilots are well represented within the entire project.

Article 3 (Functions)

1. 1. The EB is responsible for drawing up procedures to verify that ethical considerations are being properly addressed throughout the Toilet4me2 project, specifically in research and technological development as in pilots' implementation involving older people (potentially in vulnerable situations).
2. 2. The EB shall also oversee strict compliance of the ethical and moral requirements throughout the various phases of the project, according to standards of integrity, honesty, and quality.
3. 3. The EB will assess the issues that arise in the course of the project which are not yet regulated or clear enough from an ethical point of view, as well as regarding preferences, values and needs of older adults. Together with the project partners, the EB will support the clarification of these issues.
4. 4. The EB will initiate and proofread lay summaries of project results and participate in the communication towards lay people.

Article 4 (Composition and obligations of members)

1. The composition and functions of the EB are established according to the *Standards and operational guidance for ethics review of health-related research with human participants*, established by the WHO.
2. The EB is composed by 11 members: Chair and 10 other members, with the following profile:

- The Chair is the Coordinator of the Ethical tasks within the project, with relevant experience in the assessment of Ethical Compliance of digital solutions for older adults;
- There shall be minimum 4 representatives of all the pilot sites of Toilet4me2 (one per country) and they should be able to bind the institution into complying with the directives and recommendations of the EB;

- 3 primary users representatives (older adults aged over 65 or disabled), nominated by the pilot sites (and regions);
- 3 external advisors with expertise on user perspective and age-friendly environments, nominated by each one of the pilot sites.

3. The members shall be appointed for the EB for the whole period of execution of the Toilet4me2 project, being relieved of their duties with its completion. All members can withdraw themselves if they wish or need and appropriate replacements will be nominated.
4. The members of the EB must maintain secrecy and confidentiality on the contents of the discussion of all the issues raised in the meetings.

Article 5 (Operation)

1. The EB normally meets once a year, in principle in a virtual meeting, and extraordinarily when convened by the Chair. Prior to each meeting, the EB will be informed by the coordinator about project progress, as well as adverse events.
2. The EB shall act in the presence of a majority of its members, and the decisions are taken by vote, with a simple majority.
3. Decisions of the EB shall be sent to the whole consortium partners in the week following to the meeting, that will take them into account in the actions and tasks to which they respect.

NOMINATION OF MEMBERS FOR THE Ethic Board |August 2020

Chair

Name	e-Mail	Partner	Expertise/Pilot site
Carina Dantas	carinadantas@caritascoimbra.pt	Caritas Diocesana Coimbra	Portugal

Site representatives

Name	e-Mail	Partner	Expertise/Pilot site
Marta Trakul-Masłowska	marta.trakul@namiejscu.org	On-site Foundation (OSF)	Poland
George Suciu	george@beia.ro	Beia Consult International	Romania
Liesbeth Gaasbeek	l.gaasbeek@goudendagen.nl	GoldenDays	The Netherlands
Dave Dewachtere	dave.dewachtere@h-hart.be	HH	Belgium

External experts

Name	e-Mail	Affiliation	Pilot site
Iwona Przybyła	iprzybyla@um.warszawa.pl	Equal chances - Equal work" Programme for City Council	Poland

		in Warsaw https://www.linkedin.com/in/iwonaprzybyla/	
Paul Panek or Peter Mayer		TU Wien	Austria
Dr Marjo Rauhala	marjo.rauhala@tuwien.ac.at	Coordination Research Ethics TU Wien https://www.tuwien.at/en/research/rti-support/research-ethics/contact-person/	Austria

End-users representatives

Name	e-Mail	Organization	Pilot site
Justyna Kułakowska	justyna.kulakowska@far.org.pl	Foundation for Active Rehabilitation https://www.far.org.pl/select-your-language/english.html	Poland
Sandra Gosseling	sandra@gosseling.nl	Ambassador Sanmedi	The Netherlands
Marnick Donze	contact via justin.asselman@h-hart.be	User of Pamele Day Centre (priest and former teacher)	Belgium

7.4 Dutch Ethical Committee nonobligatory

metc.Utrecht

Stichting Gouden Dagen
t.a.v. M. Verburgt
Per e-mail: m.verburgt@goudendagen.nl

Ons kenmerk WAG/mb/20/500085
Datum 26 augustus 2020
Betreft METC-protocolnummer 20-549/C
Verklaring niet-WMO onderzoek

Medisch Ethische Toetsingscommissie

Contact:
Afdeling Toetsing Onderzoek

Tel 088 75 563 76
(ochtend ma t/m do)
info@metcutrecht.nl

Geachte heer/mevrouw Verburgt,

De Medisch Ethische Toetsingscommissie (METC), heeft de documenten bij onderzoeksvoorstel nummer 20/549, getiteld **"Toilet For Me/T4M2"**, ingediend door I. Gaasbeek, ontvangen en afgewogen of toetsing van het voorstel onder de WMO (Wet Medisch Wetenschappelijk Onderzoek met mensen) vereist is.

Het dagelijks bestuur van de METC Utrecht heeft op 25 augustus 2020 op basis van de hieronder genoemde documenten geconcludeerd dat het voorstel niet onder de reikwijdte van de WMO valt om één of beide van de volgende redenen:

- Er is géén sprake van medisch-wetenschappelijk onderzoek volgens de definitie van de CCMO. De definitie is te vinden op de pagina van de CCMO website: https://www.ccmo.nl/onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek/uw-onderzoek-wmo-plichtig-of-niet).

en/of

- Personen worden niet aan handelingen onderworpen of hen worden geen gedragsregels opgelegd waarvoor toetsing vereist is.

Dit betekent dat de METC geen wettelijke taak heeft bij de inhoudelijke beoordeling van dit voorstel. De commissie attendeert u er op dat zij alleen heeft afgewogen of het voorstel onder de reikwijdte van de WMO valt en daarmee is deze verklaring geen toestemming voor de uitvoer van het voorstel. U bent zelf verantwoordelijk

Bezoekadres:
Heidelberglaan 100
3584 CX Utrecht

Postadres:
Huispostnummer D01.343
Kamernummer C01.314
Postbus 85500
3508 GA Utrecht

www.metcutrecht.nl

UMC Utrecht

Prinses Máxima centrum kinderoncologie

Deelnemende instellingen: UMC Utrecht en het Prinses Máxima Centrum voor kinderoncologie

metc.Utrecht

voor de uitvoering van het voorstel volgens de geldende wet- en regelgeving waaronder, maar niet beperkt tot, de AVG (Algemene Verordening Gegevensbescherming), de WGBO en het beleid van de instelling waar het onderzoek wordt uitgevoerd. Het is niet nodig dat u de METC nader informeert over voortgang en afsluiting van het onderzoek

De commissie heeft de volgende documenten in haar afweging meegenomen:

Onderwerp	Datum ontvangst
A1-Formulier-niet-WMO Toillet For Me GD 19082020	19 augustus 2020
A1. Aanbiedingsbrief dd 19-08-2020	19 augustus 2020
Research Questions-3	19 augustus 2020

Het is raadzaam wijzigingen en/of addenda waardoor dit voorstel wel onder de reikwijdte van de WMO zou kunnen vallen, aan de METC voor te leggen.

Met vriendelijke groeten,
namens de METC,

Afdeling Toetsing Onderzoek

Aangezien voor deze brief geen wettelijke verplichting tot ondertekening geldt, wordt deze brief zonder handtekening verzonden.

Kopie

- Hoofdonderzoeker: I. Gaasbeek, per e-mail: I.gaasbeek@goudendagen.nl

To whom it may concern,

Referring to our letter of 26 August 2020 (reference number WAG/mb/20/500085) it is hereby confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the above mentioned study and that therefore an official approval of this study by the MREC Utrecht is not required under the WMO.

Yours sincerely,
on behalf of the Medical Research Ethics Committee,

Department of Research Review

Ons kenmerk WAG/mb/20/500085
Pagina's 2/2

7.5 Ethical Commitment Beia Consult International

S.C. BEIA CONSULT INTERNATIONAL S.R.L
Strada: Poiana Narciselor 12; BUCURESTI; Sector 1
Nr.ord.registru com./an : J 40/8383/1991; Cod fiscal: RO 1572582;
Cod Iban : RO52RNCB0072049692200001; Banca : BCR sector 1
Tel: +40 21 3323005
Fax: +40 21 3323006
Email: office@beia.ro
www.beia.ro

DECIZIE

Nr.7 / data 07.01.2020

D-nul Ing. Gheorghe SUCIU, în calitate de Reprezentant legal al S.C. BEIA Consult Internaţional SRL, cu sediul în Bucureşti, Str. Poiana Narciselor, nr.12, Ap.3, Sector 1, Bucureşti, Nr. R.C. J40/8383/1991, C.U.I. RO 1572582

DECIDE:

Art. 1. Se constituie comisia pentru aplicarea Codului Etic al Beia Consult Internaţional SRL, formată din următorii:

1. Dr. Mihaela BĂLĂNESCU, CS II	Preşedinte
2. Dipl. ing.Gheorghe SUCIU, CS III	Membru
3. Dr.ing. George SUCIU, CS III	Membru

Art. 2. Prezenta decizie va fi dusă la îndeplinire de către comisia pentru aplicarea Codului Etic menţionată la Art.1.

Reprezentant Legal

dl.Gheorghe SUCIU

Ghid privind respectarea eticii în proiecte/studii de cercetare–inovare cu finanțare europeană

Regulament pentru etica, conform deciziei nr 7din 07.01.2020

1. Preambul

Prezentul ghid reglementeaza in cadrul Beia Consult International SRL principiile si procedurile privind buna conduită în cercetarea științifică, dezvoltare tehnologică și inovare impuse la nivelul Uniunii Europene in cadrul proiectelor finantare din fonduri europene si in activitatea de diseminare în publicații știintifice cu mare vizibilitate internațională.
Prin bună condută in activitatea științifică se înțelege: a) Respectarea tuturor prevederilor legale:

b. Garantarea libertații în activitatea științifică;
c. Asumarea responsabilității

Acest ghid a fost elaborat in baza unor reglementari nationale si internationale specifice, cu mențiunea ca nu se substituie prevederilor legislative specifice, in vigoare, adoptate în BEIA.
În conformitate cu Regulamentul Uniunii Europene s-a impus ca, în cadrul tuturor proiectelor europene finanțate din fonduri europene precum și în activitatea de diseminare în publicații știintifice cu mare vizibilitate internațională, să fie respectate prevederile legislatiei naționale și internaționale referitoare la etica în activitatea de cercetare și inovare.

1.1 Politiciile si legislatia europeana pentru evaluarea eticii in cercetare

Din perspectiva Uniunii Europene, etica în activitățile de cercetare finanțate din fonduri europene sau activitatea de diseminare în publicații știintifice cu vizibilitate internațională mare reprezintă o componentă integrantă, dar mai ales esențială, pentru a garanta excelența în cercetare în toate domeniile de cercetare (inclusiv în cercetarea biomedicală, științe naturale și sociale). Așadar, în toate proiectele de cercetare desfasurate în cadrul programelor europeane (Horizon 2020 și respectiv Programul Cadru 2021-2027) sau în activitatea de diseminare, trebuie să se respecte cu strictețe principiile fundamentale ale eticii în cercetare (inclusiv principiul propotionalității, dreptul la viata privată, la protecția datelor cu caracter personal, protecția sănătății umane) dar și prevederile legislației naționale și internaționale referitoare la deontologia în cercetare. În acest sens, trebuie menționate inclusiv: Carta drepturilor Fundamentale a
Uniunii Europene si respectiv Convenția privind drepturile omului.
Carta drepturilor Fundamentale a Uniunii Europene (2010/C 83/02) are statut de legislație primară în cadrul Uniunii Europene. Reglementează drepturile, libertățile și principiile pentru cetățenii Uniunii
Europene. Valorile fundamentale ale Cartei sunt: deminitatea umană, libertatea, egalitatea și solidaritatea. În contextul cercetării, Carta conține câteva principii relevante, care includ: - integritatea persoanei (art.3);

- protecția datelor cu caracter personal (art.7 si 8);
- libertatea artelor și stiintelor (art.13);

Convenția Europeană a Drepturilor Omului și jurisprudența relevantă a Curții Europene a Drepturilor Omului și in special art. 8 - Dreptul la Respectarea vieții private și familiare reprezintă un alt punct de referiță in eticii în activitățile de cercetare finanțate din fonduri europene.

2. Etica în cadrul Programelor cadru europeane (Horizon 2020 și respectiv programul cadru 20212027 și a activității de diseminare în publicații științiifice cu largă vizibilitate internaționale

Se acordă o atenție sporită eticii în legislația programelor de finanțare europene precum și

activităților de diseminare în reviste științifice cu înaltă vizibilitate internațională. Astfel, la *art.4* din Evaluarea Eticii în cercetare, prevazută în regulamentul de participare la programele europene (exemplu Programul Cadru *Horizon 2020) se* stipulează faptul că se vor fi verificate sistematic acele proiecte de cercetare care conțin aspecte de etică în scopul de a eficientiza și transparentiza procesul de evaluare a eticii în cercetare.
In aceași ordine de idei, la articolul 19 din Principiile Eticii în cercetare din cadrul programului *Horizon 2020*- Regulamentul de înființare, stipulează acele principii etice catre trebuiesc respectate în activitățile de cercetare. De asemenea, se sublinează faptul că trebuie acordată o atenție deosebită principiului proportionalității, dreptului la intimitate, protecția datelor personale, integritatea fizică și mentală a unor persoane, nediscriminarea precum și obligația de a îmbunatati măsurile privind protecția sănătății umane.

2.1. Procedura de evaluare a eticii în cercetare

Se referă la: toate activitățiile finanțate sau nu din fonduri europene, inclusiv la procedura de examinare a aspectelor de etica, desfașurată chiar inainte de demararea unui proiect, suplimentar față de verificarile obișnuite precum și auditul eticii și deontologiei în activitatea științifică.
Tuturor aplicațiilor unui proiect de cercetare, respectiv întregului colectiv de autori ai unui manuscris științitific transmis la publicare li se solicită să realizeze o autoevaluare a eticii în cercetare prin completarea unui formular tabelar care cuprinde cele mai frecvente aspecte ale eticii în cercetare. Urmează apoi o etapă de evaluare științifică preliminară, după care proiectele declarate eligibile sunt supuse unei analize detaliate în panel, de experți în etică independenți.
Procedura de examinare demarează cu investigarea problematicii deontologiei și eticii în cercetare din cadrul cererii de finanțare, iar, dacă se impune, urmează o analiză ulterioară denumită evaluarea eticii. În urma acestei proceduri se pot impune pretenții privind etica în activitățile de cercetare care vor deveni obligații contractuale.
Standardele și recomandările privind etica în cercetare impuse în cadrul programelor de finanțare europene sau a jurnalelor de specialitate cu mare vizibilitate internațională vor fi riguros aplicate indiferent de țara în care se desfașoară proiectul de cercetare finanțat din fonduri europene sau studiile prezentate în manuscrisul trimis la publicare. De asemenea, tuturor instituțiilor participante/afiliate li se solicită să indeplinească cerințele Directivei Europene 95/46/UE privind protecția datelor și orice altă actualizare a standardelor sau reglementărilor care pot surveni în perioada de derulare a proiectului.
Toate institutiile beneficiare ale fondurilor europene de cercetare sau cele la care colectivul de autori au afiliere trebuie sa se conformeze cu:
a. principiile etice, inclusiv cele mai înalte standarde privind integritatea în activitatea de cercetare (Codul de conduita european pentru integritatea cercetării) și
b. legislația în vigoare la nivel internațional, european și national.
Codul de conduita european pentru integritatea cercetarii care presupune respectarea urmatoarelor principii esențiale: onestitate, fiabilitate, obiectivitate, imparțialitate, comunicare deschisă, responsabilitate și corectitudine. Din aceste considerente, se solicită beneficiarilor fondurilor europene de cercetare să se asigure că persoanele care desfașoară activități științifice vor îndeplini următoarele criterii:
- prezintă scopul și intențiile cercetării într-o manieră onestă și transparentă;
- elaborează și conduc cu atenție cercetarile asigurând astfel fiabiitatea acestora, luând în considerare impactul social;

- utilizează tehnici și metodologii (inclusiv etapa de colectare de date și management) adecvate pentru domeniul de cercetare abordat în proiect;
- Responsabilitate față de subiecțiii (resursa) de cercetare (de origine umană, animală, mediu înconjurator, obiecte cu valoare culturală);
- Asigură diseminarea rezultatelor de cercetare cu obiectivitate, acuratete și imparțialitate;
- Asigură reproductibilitatea cercetărilor ținand cont însă și de interesul legitim al beneficiarilor privind accesul la datele de cercetare;
- Este interzisă orice formă de plagiat, falsificare de date științifice;
- Se interzice dubla finanțare, conflictul de interese, informațiile false pentru accesare de fonduri sau orice abatere de la normele de etică în cercetare;

Institutiile beneficiare ale fondurilor europene de cercetare sau afiliate unei publicații științifice trebuie să isi asume pe proprie raspundere faptul ca toate activitatile științifice incluse în contractul de finanțare/manuscris au drept scop exclusiv aplicații civile.
Regulile de etică nu urmăresc să limiteze libertarea de a cerceta, ci doar să stabilească anumite limite referitoare la acele aspecte care ar putea sau nu să faca obiectul unor activități de cercetare.
Etica se aplică în toate domeniile cercetării științifice. Practic orice cercetare implică necesitatea unei evaluării a eticii.
Evaluarea eticii într-un proiect de cercetare este un proces în mai multe etape. Există o legătura strânsă între etica în activitatea de cercetare și drepturile omului.
Activitățile care implică aspecte de etica în cercetare trebuie să îndeplinească cerințele de etică stabilite ca și rezultate ale cercetării.

2.2. Documente impuse proiectelor sau studiilor științifice

Înainte de demararea unui proiect, sau a unor studii științifice care includ aspecte de etica în cercetare, se impune că fiecare participant al consorțiului să obțină următoarele documente:
a. recomandarea comisiei de etica în conformitate cu prevederile legislatiei nationale;
b. notificare sau autorizație pentru implementarea acelor activitatile științifice care ridică aspecte etice în context national și/sau european.
Documentele se vor transmite coordonatorului de proiect/autorului principal la solicitarea Comisiei. Dacă aceste documente nu sunt în limba engleza, se vor transmite în limba oficială, însoțite de un rezumat în engleză care să ateste faptul că respectivele activități științifice sunt aprobate de către autoritatea competentă.

3. PRINCIPIILE FUNDAMENTALE ALE ETICII IN CERCETARE

3.1. Să nu produca nici un prejudiciu

Se referă, în special, la ființe vii (oameni sau animale) care fac obiectul unor cercetări sau studii de orice natura, dar și acelor specialisti care sunt implicați în activități științifice care pot fi periculoase sau dăunatoare pentru personalul care participă activ cât și pentru persoanele care nu sunt implicate direct în cercetarea respectivă. Este obligatorie informarea corectă a tuturor participaților asupra existenței oricarui potențial risc care poate aparea în cursul unui proiect sau a unui studiu care este diseminat pe diferite canale științifice.

3.2. Integritatea și demnitate persoanei

Cercetarea științifică nu trebuie să lezeze demnitatea persoanelor implicate îm mod direct sau nu prin intermediul studiilor respective.
În scopul evitarii **prejudiciilor de ordin moral,** a procedeelor degradante, umilitoare, sau a oricăror eventuale atingeri aduse demnitatii umane, se va respecta dreptul la intimitate și protecția datelor.

3.3. Confidențialitatea și protecția datelor cu caracter personal

Trebuie sa se aibă in vedere faptul ca absolut toți participanții implicați voluntar sau nu într-un studiu de cercetare au dreptul la protecție. Din acest considerent este necesar sa existe o procedura de informare precum și consimțământul expres privind accepul de a fi implicat în studiul respectiv.
Subiecții individuali ai unei studiu de cercetare au dreptul la confidențialitate absolută și protecția datelor personale. Prin date personale se intelege orice informație care permite identificarea unei persoane. Datele referitoare la studii colective asupra unor subiecți umani vor fi tratate astfel încat acestea să nu fie accesibile decât subiecților individuali și cercetatorului implicat în studiul respectiv.

3.4. Mediul inconjurator

Nici o activitate de cercetare științifică nu poate să genereze rezultate cu un impact negativ pe termen scurt, mediu sau lung asupra mediului inconjurator.

3.5. Proprietatea publica sau privată

Cercetarea științifică nu trebuie să producă, în mod intenționat sau nu, daune proprietății publice sau private. Responsabilitatea tuturor prejudiciilor de acest tip aparține conducatorului cercetarii respective.

3.6. Proporționalitatea în cercetarea științifică

În activitatea științifică se va evita ca subiecții umani să fie implicați în proceduri sau experiente cu un caracter mai invaziv decât necesar sau care nu sunt prevazute în obiectivele inițiale ale studiului de cercetare.

3.7. Transparență și integritate

Calitatea cercetării și valoarea rezultatelor obținute sunt conditionate de integritatea în activitatea științifică. Onestitatea și transparența cercetării sunt condiții intrinseci pentru a asigura acuratețea și fiabilitatea științifică, fiind fundamentale pentru realizarea unui dialog constructiv cu întreaga comunitate.

3.8. Responsabilitate în diseminarea rezultatelor la cercetăriilor cu utilizare dublă

Asigură minimalizarea riscurilor asupra participanților la cercetare cât și a societății în asamblu ei de eventuale atacuri armate, teroriste.

4. ÎNCADRAREA ADECVATĂ A ASPECTELOR DE ETICĂ CARE APAR ÎN CADRUL UNEI PROPUNERI DE PROIECT/STUDIU

În confomitate cu standardele și recomandările privind etica în cercetare impuse în cadrul programului HHorizon 2020 se disting urmatoarele categorii, care pot să apara singular sau cumulat, într-un proiect de cercetare:

4.1. Cercetări în care sunt implicate subiecți umani
4.2. Date cu caracter personal
4.3. State terțe
4.4. Mediu, sănătate și securitate
4.5. Cercetări cu utilizare dublă
4.6. Conflict de interese
4.7. Alte situații

4.1. CERCETĂRI ÎN CARE SUNT IMPLICATE FIINȚE UMANE

Trebuie subliniat că acest aspect al eticii în cercetare se referă la absolut toate tipurile de activități de cercetare care includ studii sau cercetări asupra ființelor umane.
Proiectul sau studiul științific trebuie să prevada existența tuturor măsurile impuse de legislația națională, europenă și internațională privind respectarea persoanei, demnității umane, distribuția echitabilă a beneficiilor cercetarii, respectarea valorii, drepturilor și interesele tuturor participanților.
În mod obligatoriu consimțământul informat trebuie să conțină cele trei componente: a) **informații**, b) **voluntariat** și c) **competența**. Acesta presupune că, **anterior** asumării consimțite de a participa la o activitate de cercetare, toți participanții **trebuie** să dispună de informații clare și concise exprimate într-un limbaj simplu și uzual, privind: i) obiectivelor cercetării;
ii) toate aspectelor posibile, inclusiv modalitatea de păstrare și folosire a datelor/probelor colectate în proiect, distrugere sau utilizare ulterioară după perioada de implementare a proiectului respectiv; iii) posibilele beneficii, riscuri/prejudicii care pot surveni;
iv. posibilitatea de a refuză participarea sau de a se putea retrage, oricând și fără nici un fel de consecințe sau justificare, de la cercetarea respectivă;
v. metodologia sau tehnică de prelevare a datelor/probelor precum și eventualul discomfort care i se creează fiecarui participant la studiul respectiv; vi) metode alternative de tratament sau diagnostic;
vii) posiblitatea asigurării tratamentului sau a compensațiilor în cazul eventualelor prejudicii (daune) create; viii) realizarea sau nu a unor teste genetice; ix) beneficiile studiului asupra participantilor sau a altor persoane.

Se impune ca întocmirea documentului de informare a participantilor la o activitate de cercetare se va face într-o manieră accesibilă astfel încat toți participanții să aibă capacitatea să înțeleagă și să își asume consecințele consimțământului lor.

Cerințe impuse acestui tip de cercetari:

❖ Consimțământul liber și pe deplin informat al participanților la respectivul proiect/studiu de cercetare;
❖ Consimțământul expres, în scris și asumat prin semnatura al fiecarui participant;
❖ În cazul cercetărilor care implică persoane fără capacitate de exercițiu (adulți vulnerabili (bătrâni, persoane cu deficiență mentală, persoane grav bolnave, minori, etc) este obligatoriu consimțământul scris al tutorelui legal.
❖ Suplimentar, față de consimțământul scris al tutorelui legal se vor face demersuri pentru obținerea acordului în scris de la minorii care vor fi implicați în studiile respective. Este obligatoriu consimțământul scris în cazul minoriilor care vor ajunge la maturitate în perioada de derulare a proiectului;
❖ Se prezintă participanților la studiu de existența posibilității de a se obține și rezultate științifice care nu sunt neprevăzute în planul de lucru al proiectului, precum și dreptul de a fi informați asupra acestor descoperiri.
❖ Să respecte principiul maximixarii beneficiilor și să minimalizeze riscurile/prejudiciile;
❖ Se acordă o importanță deosebită asigurării stării de sănătate și siguranță a tuturor participanților;
❖ Evitarea procedurilor invazive care pot afecta fizic sau psihologic participanții la studiul respectiv.

Reglementari legale in vigoare:
- Ethics Review in FP7: Guidance for Applicants: Informed Consent;
- European Textbook on Ethics in Research: Chapter 2: Consent and Chapter 3: Vulnerable and noncompetent subjects; • Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;
- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products; • Ethical Considerations for Clinical Trials on Medicinal Products Conducted with the Paediatric Population:

Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use.

4.2. DATE CU CARACTER PERSONAL

Se referă la acele cercetări care implică colectarea sau procesarea datelor personale, indiferent de metoda utilizată pentru obținerea acestor date: interviu, chestionar direct sau on-line. În conformitate cu prevederile art. 2 din Directiva Europeană 46/1995 prin date cu caracter personal se înțelege orice informație de natură privată sau profesională care permite identificarea unei persoane (nume complet, adresă, cod numeric personal, e-mail, CV, număr de cont bancar, număr de telefon, dosar medical). Protecția datelor personale urmărește să garanteze dreptul la intimitate. Protecția datelor se referă la setul de măsuri tehnice și de securitate menit să garanteze siguranță datelelor cu caracter personal față de o eventuală posibilă utilizare a acestora în mod neprevazut, neintenționat sau chiar răuvaitor.
Asadar, se impune stabilirea unei strategii privind asigurarea acurateții informațiilor datelor

personale, accesul și păstrarea acestora.
În cercetarea științifică reprezintă o adevarată provocare utilizarea și transmiterea datelor, respectând în același timp, obligația de a proteja toate datele de identificarea astfel încât să fie garantată intimitatea personală. Datele personale necesare în activitățile de cercetare pot include urmatoarele tipuri de informații: genetice, de sănătate, cazier judiciar, deplasări, orientare religioasă, orientare sexuală, etnie. Procesarea datelor cu caracter personal presupune orice operație sau set de metode manuale sau automate efectuate asupra unor informații de acest tip, care includ:

- Colectarea (digitală, audio sau video)
- Înregistrarea;
- Organizarea și stocarea (LAN, WAN sau cloud);
- Adaptarea sau modificarea;
- Recupere și consultare;
- Utilizare;
- Divulgare prin transmitere, diseminare sau punere la dispoziție prin orice alt mijloc (partajare, schimb, transfer);
- Ordonare sau combinare;
- Blocare, ștergere sau distrugere.

În mod uzual, procesarea datelor cu caracter personal implică folosirea acestora în scop stiintific, chiar în cazul în care aceștia nu sunt participanți activi în proiect (persoanele chestionate, voluntari, pacienți). *De exemplu*: crearea unei liste de participant sau liste de e-mail, gestionarea unei baze de date, date financiare privind costurile de personal, pontajele, planul de lucru al proiectului care include numele unor persoane.
Trebuie menționat faptul că oricine are dreptul să solicite ștergerea sau încetarea procesării datelor sale personale.
Datele care au fost anonimizate nu se supun acestor reglementari !
Se consideră ca fiind anonimizată o persoană dacă pentru identificarea să este necesar un efort ridicat.
Cerinte impuse acestui tip de cercetari:

- ✓ Colectarea datelor trebuie sa fie adecvată și relevantă;
- ✓ Datele pot rămane identificabile, codificate sau complet anonimizate;
- ✓ Procesarea datelor personale trebuie sa se facă în mod corect cu respectarea prevederilor legislației în vigoare la nivel national și european;
- ✓ Procurarea și procesarea datelor cu caracter personal se face doar într-un scop precis și bine justificat;
- ✓ se va evita utilizarea lor în mod excesiv;
- ✓ mentinerea acuratetii și actualizarea lor;
- ✓ nu sunt păstrate decât până la finalizarea perioadei de implementare a proiectului care a necesitat colectarea/ procesarea lor;
- ✓ procesarea datelor cu caracter personal se face în concordanță cu dreptul individual al fiecarei persoane;
- ✓ securizarea accesului la datele personale;
- ✓ se interzice transferul acestor informații către alte state în lipsa unei protecții adecvate.
- ✓ Se va acordă o atenție deosebită procesării datelor personale cu caracter mai sensibil cum sunt: rasă, etnie, păreri politice, religie, apartenența sindicală, stare de sănătate fizică sau psihică, viata sexuală, cazier juridic.
- ✓ Consimțământul informat, în scris, al fiecărui participant privind autorizarea utilizării,

procesarii și stocării datelor personale în scop științific;

În mod obligatoriu, cererile de finanțare trebuie să conțină o prezentare generală a activităților științifice în care presupun colectarea, procesarea sau transferul de date personale includ o descriere detaliată a tuturor metodelor utilizate în vederea respectării legislației în domeniu. De asemenea, se vor transmite copii ale tuturor autorizatiilor obtinute la nivel local și national. În cazul în care nu s-au obținut aceste autorizatii înainte de transmiterea cererii de finanțare, se va preciza în mod obligatoriu o dată la care se estimează că se vor obține aceste autorizații. *Reglementari legale in vigoare*:

- Leg. nr. 677/ 2001
- General Data Protection Regulation (GDPR)
- *Charter of Fundamental Rights*
- *Treaty on the Functioning of the European Union* • Ethical Review in FP7: Data protection and privacy ethical guidelinesEuropean Textbook on Ethics in Research: Chapter 4: Privacy and confidentiality;
- Treaty on the Functioning of the European Union, article 16
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data; • Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
- UNESCO International Declaration on Human Genetic

4.3. STATE DIN AFARA UNIUNII EUROPENE

Se acordă o atenție sporită acelor proiecte de cercetare care includ în planul de activități:

- ✓ cercetări coodonate sau în colaborare cu țări din afara Uniunii Europene;
- ✓ existența unor specialiști sau participanți din țări terțe;
- ✓ resurse importate sau exportate din aceste tari;

De subliniat este faptul că toate activitățile de cercetare care se desfasoară în aceste state trebuie să indeplinească obiectivele generale ale Uniunii Europene !!!
Pot exista unele probleme de etica în cazul colaborărilor științifice cu țările terțe, și în special cu țările în curs de dezvoltare. Acește țări se confruntă cu sărăcie, boli, nivel ridicat de alfabetism, absența infrastructurii și a resurselor materiale. Din aceste considerente, cele mai frecvente probleme de etică care apar sunt următoarele:

- ✓ exploatarea participanților în activități de cercetare;
- ✓ exploatarea resurselor naturale;
- ✓ existența unor riscuri pentru echipa de proiect (conflicte armate, presiuni politice, epidemii);
- ✓ derulare de cercetări care sunt interzise în Uniunea Europeană.

O cerere de finanțare în care este implicat un partener din state din afara Uniunii Europene trebuie, în mod obligatoriu să le includă următoarele **puncte cheie**:

1. *recunoașterea responsabilității și asigurarea măsurilor de asistență* dacă este necesar;
2. trebuie să se ia în considerare contextul politic, social și cultural care pot avea eventualele implicații asupra gradului de risc al participanților, cercetatorilor. Barierele culturale, economici,

lingvistice, nivelul de educație și de analfabetism care îngreunează indeplinirea procedurii de obținere a consimțământului informal expres al tuturor participanților potențial vulnerabile;
3. aplicarea și respectarea cu strictețe a standardelor de integritate în cercetare și a eticii în cercetare in vigoare la nivel național și european în statele aflate în afară jurisdicția Uniunii Europene. **Trebuie retinut faptul că nu sunt garantate fondurile europene de cercetare în cazul activităților științifice care se desfășoară în afara Uniunii Europene, dacă acestea sunt interzise în toate țările membre ale UE**. **4)** respectarea legilor in vigoare în țară terță înseamnă în primul rând cunoasterea legislației local, a autorităților competente, a autorizațiilor necesare, etc;
5. contactarea și menținerea legăturii cu organizațiile neguvernamentable și caritabile locale;
6. trebuie să se ia în considerare și necesitatea obținerii autorizațiilor locale privind etica în cercetare și utilizarea infrastructurii științifice, chiar dacă acesta există și corespunde necesităților proiectului.

Cerințe impuse acestui tip de cercetări:
✓ o justificare stiintifică solidă privind necesitatea implicării în consorțiu proiectului a țărilor terțe;
✓ analiza cost-beneficiu care va include o detaliere a activitătilor ce se vor derula în țările terțe
✓ Cercetarile incluse în cererea de finanțare respectă deontologia în cercetarea științifică europeană. La depunerea proiectului, beneficiarii își vor asuma sub semnatură faptul că autoevaluarea eticii întrunește condițiile impuse de legislația națională, europeană și internațională; ✓ se asigure protecția drepturilor și a interesele tuturor participanților;
✓ exista o repartitie echilibrata a beneficiilor cercetarii;
✓ obținerea consimțământului informat în scris de la toți participanții la studiu de cercetare;
✓ utilizarea resursele locale de orice tip (materială, umană, flora faună, etc.) din țarile terțe să se facă cu respectarea tradițiilor culturale și compensarea adecvată. Se impune obținerea autorizațiilor sau notificărilor locale privind respectarea deontologiei în cercetarea științifică însotite in mod obligatoriu si o confirmare din partea unei autoritatii de etica din Uniunea Europeana;
✓ importul sau exportul de materiale din tarile terte trebuie să se facă în conformitate cu prevederile legislației naționale și internaționale și să fie însotite de un contract care și conțină o descriere a condițiilor de export, termeni de utilizare și eventualele măsuri de împarțire a beneficiilor;

✓ să se evite standardul dublu privind etică în cercetarea științifică;
✓ analiza risc-beneficiu referitoare la detașarea unor membri ai echipei de proiect în țările din afara Uniunii Europene. Acesta analiza va include în mod obligatoriu măsurile prevăzute pentru asigurarea siguranței acestora (ex. asigurare de sanatate, puncte de contact telefonic, interzicerea desfasurarii oricarei activități solidare, consiliere, etc).

Reglementări legale în vigoare:
d. UNESCO's Declaration on Science and the Use of Scientific Knowledge

Nuffield Council on Bioethics: The Ethics of Research Related to Healthcare in Developing Countries;
e. Ethics Review in FP7: Ethics in research and international cooperation

European Textbook on Ethics in Research: Chapter 6: Justice in Research: Research in developing

countries; • Ethical and Regulatory Challenges to Science and Research Policy at the Global Level: Chapter 3: Scientific-Technological Divides and Benefit Sharing;
f. *Declaration of Helsinki;*
g. *UN Convention on Biological Diversity;*
h. *Nagoya Protocol on Access and Benefit Sharing;*

4.4. IMPACTUL CERCETARILOR ASUPRA MEDIULUI INCONJURATOR, SĂNĂTATII ȘI SECURITATII

Se refera la acele cercetari care pot avea impact negativ asupra mediului, sanatatii si securitatii participantilor prin designul si/sau dezvoltarea unor noi produse, procese, tehnologii sau ca efect secundar al metodologiilor sau tehnologiilor utilizate in activitatile stiintifice.

4.4.1. MEDIUL INCONJURATOR

✓ In toate activitatile stiintifice se va aplică și respectă cu strictețe prevederile legale în vigoare la nivel national, european și international acordându-se o atenție deosebită principiului precauției, conservarii habitatului natural și controlului poluării;
✓ Evaluarea impactului noi tehnologii (produs, proces) dezvoltate asupra mediului astfel încât să fie minimalizate eventualele riscuri de poluare și/sau biodiversității;
✓ Se impune ca în acest tip de proiecte să existe o analiză risc-beneficiu;
✓ Obținerea autorizațiilor de producere, utilizare a organismelor modificate genetic;
✓ Obținerea autorizațiilor de mediu la nivel local și național;
✓ Sunt strict interzise toate cercetări care pot genera un efect negativ asupra speciilor pe cale de disparitie sau în ariile protejate;

Reglementari legale in vigoare
i. EU Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p.7);
j. EU Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (OJ L 103, 25.4.1979, p.1);
k. EU Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 103, 25.4.1979, p.1);
l. Cartagena Protocol on Biosafety;
m. EU Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p.1);

n. EU Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p.19);
o. EU Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p.1);

p. EU Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).
q. OUG 57/2007 actualizată

4.4.2. SĂNĂTATE ȘI SECURITATE

✓ În toate activitățile de cercetare trebuie să constituie o prioritate garantarea sănătatii și securității tuturor participantiilor;
✓ Toate proiectele de cercetare trebuie sa conțină o estimare a potențialelor riscuri asupra sănătății și securității participanților precum și măsurile preconizate pentru a le minimaliza;
✓ Respectarea bunelor practici în cercetarea științifică pentru a preveni eventualele riscuri de sănătate și securitate;
✓ Respectarea legislatiei în vigoare la nivel national, european și internațional privind controlul sănătății publice și protecției muncii;
✓ În cazul în care realizarea obiectivelor științifice ale proiectului de cercetare implică utilizarea unor substanțe chimice toxice și/sau potential explozive se impune ca membri echipei de proiect să fie instruiți în manipularea, depozitarea și eliminarea acestui tip de reactivi;
✓ Proiectele care urmăresc dezvoltarea de noi compuși/produși cum sunt de exemplu nanomaterialele trebuie să includă o evaluarea a potențialelor riscurilor care pot surveni;
✓ Cercetările asupra materialelor radioactive trebuie să respecte legislația în vigoare la nivel national si european referitoare la stocarea, manipularea și eliminarea acestei categorii de materiale. Deversarea materialelor radioactive în mediu este interzisă.
✓ Obtinerea autorizatiei de a derula cercetari asupra unor specii pe cale de disparitie/in arii protejate;
✓ Documentul care să ateste nivelul de clasificare al securitatii în muncă pentru laboratorul de cercetare respectiv;
Pentru evitarea oricăror prejudicii aduse sănătății și securității participanților la o activitate de cercetare se vor stabili și respecta următoarele proceduri:
✓ Fiecare membru al echipei de cercetare va completa zilnic note și observații experimentale referitoare la activitatea stiintifica la care a participat;
✓ La formarea și completarea echipei de cercetare va prima criteriul competenței și expertizei în domeniul științific al proiectului;
✓ Cercetătorii care fac muncă de teren vor pastra permanent contactul telefonic cu unitatea centrală de cercetare;
✓ Realizarea unor evaluari complete privind eventualele riscuri care pot surveni la amplasamentele in care se desfasoara munca de teren;
✓ Notificarea formala a autoritatilor competențe privind desfasurarea unor activitati de cercetare într-o anumită locație;
✓ Obținerea eventualelor autorizații necesare derulării cercetărilor;
✓ Pregatirea și instruirea cercetătorilor asupra tehnicilor de gestionarea conflictelor, amenințări, abuzuri sau alte situatii compromițătoare;
✓ După încheierea unei sesiuni de studii de teren se vor organiza sedințe și se va realiza o evaluare a siguranței acestor cercetări;
✓ Raportarea tuturor incidentelor legate de sanatatea și siguranța echipei de proiect.

Reglementari legale in vigoare:
r. EU Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of the workers to risks

arising from physical agents (OJ L 114, 27.4.2006, p.38);
s. A Code of Practice for the Safety of Social Researchers;

4.5. CERCETARI CU DUBLĂ UTILIZARE

Se refera la:
t. cercetări care conduc la obținerea de rezutate științifice care pot fi utilizate și în scop militar (terorism, etc);
u. cercetări asupra unor agenți patogeni de origine umană, animală sau vegetală, substanțe chimice cu toxicitate ridicată, materiale radioactive care pot cauza grave prejudicii sănătății umane, animale sau mediului înconjurator;
v. cercetări care utilizează informații sau materiale tehnice clasificate sau materiale periculoase.

Posibila utilizare dublă a noilor rezultate stiintifice și tehnologii crează probleme de etica pentru comunitatea științifică priviind responsabilitatea de a preveni utilizarea dual㠊n general, în Uniunea Europeană sunt eligibile la finanțare doar cercetările cu aplicații civile. Dar, există posibilitatea de finanțare în cadrul programului Horizon 2020 și a acelor cercetari cu utilizare dublă în cazul în care sunt prevazute măsuri speciale de abordare și gestionare a unor posibilele utilizări necorespunzatoare.

Cerințe impuse acestui tip de cercetări:
✓ să se stabilească o strategie globală detaliată a particularitatilor cercetării și asigurarea maăsurilor necesare de salvgardare;
✓ se acordă o atenție deosebită transferului transfrontalier a materialelor cu utilizare dublă, tehnologiilor sau informațiilor clasificate. În acest caz se impune aplicarea cu strictețe a reglementărilor legale în vigoare privind transportul.

Astfel de proiecte impun o abordare are să demonstreze în mod clar și evident următoare aspecte:

a) Conștientizarea posibilelor riscuri

Solicitanții proiectului trebuie să fie conștienți de potentiala utilizare dublă a cercetărilor și implicit de eventualele riscuri directe asupra participanților și societate. Cererea de finantare trebuie să includa o evaluare a gradului de biosecurizare, un sistem pentru denunțarea timpurie a problemelor de biosecuritate și biosiguranță, măsuri de pregatire și instruire;

b) Strategie a situatiilor de risc

Solicitanții proiectului trebuie sa elaboreze o strategie coerentă (pe și după perioada de implementare a proiectului) care include o prezentare detaliată a măsurilor adecvate pentru gestionarea unor situații perioculoase (controlul accesului, alocarea nivelului de confidențialitate, monitorizarea tuturor procedurilor, raportarea tuturor incidentelor survenite, etc) de materiale sau informații clasificate. Procedurile de gestionare a riscurilor de biosecuritate și biosigurantă trebuie să respecte standardele nationale și internaționale existente.

c) Existența unui expert independent

Se impune introducerea în echipa de proiect sau în consiliul consultativ a unui consilier independent de etică, expert în biosecuritate și a cercetărilor cu utilizare dublă. Rolul acestui expert este acela de a supraveghea și a asista la elaborarea unui sistem de management al riscurilor.

d) Strategia de diseminarea si exploatare a rezultatelor stiintifice

Va fi elaborată cu experți independenți astfel încât să se asigure minimalizarea eventualelor potentiale consecințele comunicării pe scara largă a rezultatelor cercetărilor cu utilizare dublă. *Reglementari legale in vigoare:*

w. Guidance document: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research;
x. WHO Biorisk management: Laboratory biosecurity Guidance;
y. Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items;
z. Annex I of Regulation (EU) No 388/2012 of the European Parliament and of the Council of 19 Aprilie
2012;
aa. European Textbook on Ethics in Research: Chapter 7: Science and Society: Dual use;
bb. Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences by S. Miller and M.J. Selgelid.

4.6. CONFLICT DE INTERESE

Se referă la situațiile în care obiectivitatea, acuratețea, eficiența si/sau imparțialitatea unuia sau mai multi membri ai echipei de proiect este amenințată de un interes distinct de preocupările științifice sau etice ale cercetării. Un conflict de interese apare în cazul în care un membru al echipei de cercetare are un beneficiu semnificativ, direct sau indirect (pentru sine, rude sau afini de până la gradul IV) rezultat din derularea proiectului și care poate să compromită integritatea proiectului respectiv. Avantajele personale pot fi de tip financiar sau de orice altă natura: (oportunități de cariera, promovare unor relații personale, etc) pot afecta competența profesională a unui cercetator cauzând încalcarea deontologiei în cercetare. Nu se consideră conflict de interese cazul în care:

✓ componența echipei de proiect este alcatuită pe baza de competență și expertiza necesară realizării obiectivelor proiectului;
✓ gestionarea fondurilor alocate proiectului se face în conformitate cu prevederile legale în vigoare;

Cerințe impuse pentru evitarea conflictului de interese:

✓ toți cercetătorii își desfașoară activitatea în mod competent și imparțial;
✓ toți cercetatorii au obligația de a declara în mod transparent existență oricărui posibil conflict de interese și să il gestioneze eficient astfel încât să nu compromită integritatea proiectului.

4.7. Alte situații

Expert în etică/Consilieri de etică/consiliul consultativ în proiecte de cercetare din fonduri europene

Introducerea în managementul proiectului a unui expert în etică sau a consiliului consultativ de etică facilitează gestionarea eventualelor probleme de etică care pot surveni.

În situația în care un proiect de cercetare poate ridică probleme de etică mai complexe se impune numirea unui consiliu consultativ de etică alcătuit din mai mulți experți cu expertize diferite care vor asigura respectarea standardelor eticii în cercetare.

Conditii impuse pentru numirea expertului în etică/consiliului consulativ de etică:

- ✓ Nu fac parte din instituția gazdă;
- ✓ Sunt independenți
- ✓ Nu există nici un fel de conflict de interese
- ✓ Sunt resposabili de raportarea regulată catre Comisie/Autoritatea de finanțare europeană a eventualelor preocupari de etică pot surveni în implementarea proiectului și de integritatea cercetărilor; ✓ Activează pe toate perioada de derulare a proiectului;

Cererea de finantare trebuie să includă:

cc. numele si datele de contact ale acestor experți;

dd. o descriere detaliată a activităților pe care le desfasoară în proiect precum și rezultatele preconizate;

ee. declarația în scris asumată de fiecare dintre acești experți privind lipsa conflictelor de interese

7.6 Ethical Committee H-Hart Belgium

Afz.: Commissie voor Medische Ethiek

Dhr. Dave Dewachtere
N/A
ALHIER

contact	telefoon	e-mail	
Commissie voor medische Ethiek	+32 (0)9 332 41 81	Ethisch.comite@uzgent.be	
Ons kenmerk	**Uw kenmerk**	**datum**	**pagina**
BC-08632	NVT	30/11/2020	1/3

Betreft:

Advies voor monocentrische studie met als titel:

'Toilet4me (T4ME2): Eropuit dankzij toegankelijk toilet'

B.U.N.: B6702020000889

Adviesaanvraagformulier 2/10/2020 ontvangen dd 15/10/2020
CV
Financiële overeenkomst 2/10/2020 financieel plan + bewijs financiering
Rekruteringsmateriaal: tertiaire deelnemers
Patiënteninformatie- en toestemmingsformulier 2/10/2020
Vragenlijsten
Begeleidende brief 2/10/2020
Patiëntenmateriaal: Factsheet en guidelines

Advies werd gevraagd door: Dhr. Dave Dewachtere

BOVENVERMELDE DOCUMENTEN WERDEN DOOR HET ETHISCH COMITÉ BEOORDEELD. ER WERD EEN POSITIEF ADVIES GEGEVEN OVER DIT PROTOCOL OP 16/11/2020 INDIEN DE STUDIE NIET WORDT OPGESTART VOOR 16/11/2021, VERVALT HET ADVIES EN MOET HET PROJECT TERUG INGEDIEND WORDEN.
Vooraleer het onderzoek te starten dient contact te worden genomen met HIRUZ CTU (09/332 05 00).

THE ABOVE MENTIONED DOCUMENTS HAVE BEEN REVIEWED BY THE ETHICS COMMITTEE.A POSITIVE ADVICE WAS GIVEN FOR THIS PROTOCOL ON 16/11/2020 IN CASE THIS STUDY IS NOT STARTED BY 16/11/2021, THIS ADVICE WILL BE NO LONGER VALID AND THE PROJECT MUST BE RESUBMITTED.
Before initiating the study, please contact HIRUZ CTU (09/332 05 00).

DIT ADVIES WORDT OPGENOMEN IN HET VERSLAG VAN DE VERGADERING VAN HET ETHISCH COMITE VAN 17/11/2020.
THIS ADVICE WILL APPEAR IN THE PROCEEDINGS OF THE MEETING OF THE ETHICS COMMITTEE OF 17/11/2020.

* *Het Ethisch Comité werkt volgens 'ICH Good Clinical Practice' - regels*
* *Het Ethisch Comité bekijkt enkel of een gunstig advies niet bekeken dat het Comité de verantwoordelijkheid voor het onderzoek op zich neemt. Bovendien dient U er over te waken dat Uw mening als betrokken onderzoeker wordt weergegeven in publicaties, rapporten voor de overheid enz., die het resultaat zijn van dit onderzoek.*
* *In het kader van 'Good Clinical Practice' moet de mogelijkheid bestaan dat het farmaceutisch bedrijf en de autoriteiten inzage krijgen van de originele data. In dit verband dienen de onderzoekers erover te waken dat dit gebeurt zonder schending van de privacy van de proefpersonen.*
* *Het Ethisch Comité benadrukt dat het de promotor is die garant dient te staan voor de conformiteit van de anderstalige informatie- en toestemmingsformulieren met de nederlandstalige documenten.*
* *Geen enkele onderzoeker betrokken bij deze studie is lid van het Ethisch Comité.*

ALGEMENE DIRECTIE
Commissie voor Medische Ethiek

VOORZITTER
Prof.dr. P. Deron

SECRETARIS
Prof.dr. R. Peleman

STAFMEDEWERKER
Muriel Fouquet
T +32(09) 332 33 36
Sara De Smet
T +32(09) 332 68 55
Sabine Van de Moortele
T +32(09) 332 69 54

SECRETARIAAT
Sebastien Callewaert
T +32(09) 332 41 81
Marleen De Meyer
T +32(09) 332 05 06
Charlotte De Vlieger
T +32(09) 332 22 69
Sandra De Puspo
T +32(09) 332 26 69
Ann Heerebaucke
T +32(09) 332 22 56

INGANG 75
ROUTE 7522

UZ GENT
UNIVERSITEIT

Universitair Ziekenhuis Gent
C. Heymanslaan 10 | B 9000 Gent

* *Alle leden van het Ethisch Comité hebben dit project beoordeeld. (De ledenlijst is bijgevoegd)*
* *The Ethics Committee is organized and operates according to the 'ICH Good Clinical Practice' rules.*
* *The Ethics Committee stresses that approval of a study does not mean that the Committee accepts responsibility for it. Moreover, please keep in mind that your opinion as investigator is presented in the publications, reports to the government, etc., that are a result of this research.*
* *In the framework of 'Good Clinical Practice', the pharmaceutical company and the authorities have the right to inspect the original data. The investigators have to assure that the privacy of the subjects is respected.*
* *The Ethics Committee stresses that it is the responsibility of the promotor to guarantee the conformity of the non-dutch informed consent forms with the dutch documents.*
* *None of the investigators involved in this study is a member of the Ethics Committee.*
* *All members of the Ethics Committee have reviewed this project. (The list of the members is enclosed)*

Namens het Ethisch Comité / On behalf of the Ethics Committee

Prof. dr. P. Deron
Voorzitter / Chairman

CC: UZ Gent – HIRUZ CTU
FAGG - Research & Development; Victor Hortaplein 40, postbus 40 1060 Brussel

Ledenlijst 2019-2023:

Voorzitter: Prof.dr. P. DERON (UZG – chirurg, ♂)
Secretaris: Prof.dr. R. PELEMAN (UZG – internist, ♂)

Leden:
Prof.dr. mr. T. BALTHAZAR (UG - jurist, ♂)
Dhr. K. BENHADDOU (menswetenschapper, ♂)
Prof.dr. W. CEELEN (UZG – chirurg, ♂)
Prof.dr. J. DECRUYENAERE (UZG – internist, ♂)
Dhr. C. DEMEESTERE (UZG – verpleegkundige, lic. Medisch sociale wetenschappen, ♂)
Prof. dr. K. DHONDT (UZG – (kinder)psychiater, ♀)
Prof.dr. D. DE BACQUER (UG - statisticus, ♂)
Dr. K. DE GROOTE (UZG – kindercardioloog, ♀)
Prof.dr. M. De MUYNCK (UZG – fysiotherapeute, ♀)
Dhr. G. DE SMET (UZG – verpleegkundige, - lic. Medisch sociale wetenschappen ♂)
Mevr. M. FOUQUET (UZG – verpleegkundige, ♀)
Dr. L. GOOSSENS (UZG – neonatoloog, ♀)
Dr. S. JANSSENS (UZG – geneticus, ♀)
Mevr. K. KINT (UZG – apotheker, ♀)
Prof.dr. F. MORTIER (UG – moraalfilosoof, ♂)
Prof.dr. W. NOTEBAERT (UG – psycholoog, ♂)
Dr. N. PETERS (UZG – fertiliteitsarts, ♀)
Prof.dr. R. PIERS (UZG - geriater, ♀)
Prof.dr. R. RUBENS (UZG – endocrinoloog, ♂)
Prof.dr. P. SCHELSTRAETE (UZG – kinderpneumoloog/infectioloog, ♀)
Prof.dr. S. STERCKX (moraalfilosoof, ♀)
Mevr. C. VANCAENEGHEM (patiëntvertegenwoordiger)
Dhr. B. VANDERHAEGEN (UZG - moraaltheoloog, ♂)
Prof.dr. W. VAN BIESEN (UZG – nefroloog, ♂)
Dr. J. VAN ELSEN (huisarts, ♂)
Dr. G. VAN LANCKER (UZG – klinisch farmacoloog, ♀)
Prof.dr. K. VAN LIERDE (UG – logopediste, ♀)
Prof.dr. H. VERSTRAELEN (UZG – Vulva-arts, ♂)