Research & Innovation Actions

5G PPP Research and Validation of critical technologies and systems: Enabling Smart Energy as a Service via 5G Mobile Network advances.

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Enabling Smart Energy as a Service via 5G Mobile Network advances

Deliverable 8.1

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Author(s): M. Bertoncini (ENG)

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Abstract:

The NRG-5 project itself does not intend to collect, store or handle any personal data and would not need to identify/ recruit any humans as research participants. Yet, as it runs pilots where individuals may be involved and consumers' energy behaviour might be mined, it has to define the procedures and methodology so that the relevant ethics are respected.

This deliverable describes the framework with respect to Ethics and Privacy issues in all implementation aspects of the NRG-5 project. It describes the most important policies, regulations, principles and definitions of data protection law in the European Union and presents the actions and authorizations by the National Authorities. Moreover it described the Ethics Board Organization. Finally it describes the procedures for data collection, storage, protection, retention and destruction and associated Informed Consent procedures.

Finally a number of templates are provided as Appendix.

Disclaimer

The NRG-5 Consortium is the following:

Participant number	Participant organisation name	Short name	Country
01	Engineering-Ingegneria Informatica SPA	ENG	Italy
02	THALES Communications & Security	TCS	France
03	SingularLogic S.A.	SiLO	Greece
04	ENGIE	ENGIE	France
05	Romgaz S.A	RGAZ	Romania
06	ASM Terni SpA	ASM	Italy
07	British Telecom	BT	UK
08	Wind Tre	WIND3	Italy
09	Hispasat S.A.	HIS	Spain
10	Power Operations Limited	POPs	UK
11	Visiona Ingenieria De Proyectos SI	VIS	Spain
12	Optimum S.A	OPT	Greece
13	Emotion s.r.l	EMOT	Italy
14	Rheinisch-Westfälische Technische Hochschule Aachen	RWTH	Germany
15	Jožef Stefan Institute	JSI	Slovenia
16	TEI of Sterea Ellada/Electrical Engineering Dept.	TEISTE	Greece
17	University Pierre et Marie Curie	UPMC	France
18	Centro Romania Energy	CRE	Romania
19	Rutgers State University of New Jersey	Rutgers	USA

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12/12/17	1.0	M. Bertoncini	Document Finalization

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List of Abbreviations

AMI	Automatic Metering Infrastructure
DPL	Data Protection Law
EEA	European Economic Area
EU	European Union
GDPR	General Data Protection Regulation
JEU	Court of Justice of the European Union
IDPA	Italian Data Protection Authority
PPP	Public Private Partnership

1 Introduction

This deliverable sets the framework with respect to Ethics and Privacy issues in all implementation aspects of the NRG-5 project.

Chapter 2 describes the most important policies, regulations, principles and definitions of data protection law in the European Union. Moreover, it presents the partner specific National Legislation.

The rest of the deliverable addresses the requirements set in WP7:

- Chapter 3 presents the relevant national data protections authorities associated with each partner.
- Chapter 4 describes the procedures for data collection, storage, protection, retention and destruction
- Chapter 5 describes the procedures for involving/recruiting research participants in the NRG-5 project and pilots.
- Chapter 6 describes the Informed Consent procedures in regard of the collection, storage and protection of personal data

The appendixes provide the templates for

a) The “Individual Ethics & Confidentiality Statement Form”, which all NRG-5 Consortium Members involved with sensitive and personal data should sign

b) The “Pilot Confidentiality & Ethical Forms”, which will be signed by the NRG-5 Consortium Members involved in the pilots and interact with volunteers

c) The “Data Handling Informed Consent”, which will be signed by the NRG-5 Consortium Members involved in the data handling and the volunteer that provides the data.

d) The “Informed Consent Certificate” for data collection, storage, protection, retention and destruction, which will be signed by the NRG-5 consortium members interacting with volunteers and volunteers themselves.

2 Policies and Regulations on Ethical Issues

2.1 Ethical Issues in NRG-5

NRG-5 targets the Smart Energy sector utilizing the 5G innovations. In the majority of the experiments no ethical issues are predicted; however especially in the case of Automatic Metering Infrastructure (AMI) and utilization of drones for Preventive Maintenance some clarifications are given.

The following issues will deserve particular attention:

- Careful selection of participants will be done in close collaboration with utilities in compliance with ethical practices already in place;
- Clear explanation in plain language will be given of the project (purpose, practicalities, potential consequences), both written and oral;
- Use of the teach – back principle to reassure understanding;
- Written and signed Informed consent from participants and their family caregivers;
- Full up listing and transparency on all data that will be gathered;
- Options and consequences of drop out during the project;
- Who to contact in case of inquiry and when.

Particular emphasis will be made on the types of information shared, and the ability to obtain informed consent from some of the participants. When informed consent is not possible, the project will work with the care provider to establish safe ways for obtaining consent from a person related to the service user, such as a next of kin, or someone with powers of attorney.

To perform trials related to treatment of personal sensitive information there are several directives at European level that will be met. Member states can transpose these into more concrete national implementations. The consortium members of this project declare that the proposal conforms to current legislation and regulations in the countries where the research will be carried out. The use of data will be strictly limited to the context of the project and participants have full right to drop out and ask for their data to be removed.

The NRG-5 use case trials will operate a strict information security policy that will apply to the project. The policy, and the information security risk register, will be adopted by the project. As a direct result, all participants data will be anonymised, and access to data will obey to clearly defined rules. All systems will be developed in strict compliance with ISO 27001 and ISO 25237 for pseudonymisation of data.

2.2 The EU's data protection approach

At European level, the most important elements of legislation in the field of data protection are article 8 of the Charter, the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, referred to as the Data Protection Directive, and, as its successor, the Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, commonly known as the General Data Protection Regulation.

The EU General Data Protection Regulation (GDPR) replaces the Data Protection Directive 95/46/EC – enforcement date: 25 May 2018 – and was designed to harmonize data privacy laws across Europe, to protect and empower all EU citizens data privacy and to reshape the way organizations across the region approach data privacy.

The most significant changes introduced by the Regulation.

- The scope of application of the European data protection legislation is broadened: the new Regulation, in fact, shall also be applied to data controllers established outside the Union when data processing, aimed at offering them goods and/or services or at monitoring their behaviour concerning data subjects established in the Union.
- The requirements to obtain valid consent become stricter: in particular, to be valid, consent must be given by a clear affirmative act. Thus, silence, pre-ticked boxes or inactivity cannot constitute valid consent. Furthermore, data subjects may always revoke their consent to data processing without any limitation.
- Right to be forgotten (i.e. the right of data subjects to obtain the definitive deletion of their data processed and stored by data controllers) and the right to data portability from a data controller to another one are now expressly provided for.
- Principles of data protection "*by design*" and "*by default*" are introduced. The latter consist of the duty for the data controller to, respectively, properly protect personal data at the time of their collection and during the whole duration of the processing, and to only use data collected for purposes for which data subjects have given their consent and not beyond the minimum necessary time for the achievement of those purposes.
- Data controllers shall carry out a "*data protection impact assessment*" when the data processing at issue is likely to result in a high risk to subjects' rights and freedoms and they shall maintain records of processing activities under their responsibility.
- As soon as they become aware that a personal data breach has occurred, data controllers shall notify the national supervisory authority and/or data subjects of the data breach at issue.
- The new role of the data protection officer (DPO) is introduced for public entities and for private entities that process special categories of data (for instance, sensitive data) or whose data processing consists in the regular and systematic monitoring of data subjects on a large scale. Data protection officers are data protection law and practices experts – employees of the data controller or outside consultants – who shall inform and advise the data controller of its obligations pursuant to the Regulation, monitor its compliance with the latter, provide the abovementioned data protection impact assessments and liaise with data subjects and with the DPA.
- Data controllers and processors can obtain a certification from credited certification bodies or by the competent supervisory authority demonstrating the compliance of their data processing with the Regulation.
- Penalties become significantly stricter

The General Data Protection Regulation ('GDPR'), due to come into effect on 25 May 2018, provides a modernised, accountability-based compliance framework for data protection in Europe.

Data Protection Officers ('DPO's) will be at the heart of this new legal framework for many organisations, facilitating compliance with the provisions of the GDPR. Under the GDPR, it is mandatory for certain controllers and processors to designate a DPO. This will be the case for all public authorities and bodies (irrespective of what data they process), and for other

organisations that - as a core activity - monitor individuals systematically and on a large scale, or that process special categories of personal data on a large scale[1]

Provisions, relating to data protection, can be found both in primary and secondary law of the EU:

Primary Law

The Charter of Fundamental Rights not only guarantees the right to private and family life (art. 7) but also establishes the right to the protection of personal data (art. 8):

1. *Everyone has the right to the protection of personal data concerning him or her.*
2. *Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.*
3. *Compliance with these rules shall be subject to control by an independent authority.*

Additionally the Treaties include explicit reference to the right to the protection of personal data as well. Art. 16 TFEU and art. 39 TEU both recognize the aforementioned right. The CJEU ensures the uniform application of this right.

Secondary Law

- Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data
- Directive 95/46/EC of the European Parliament and 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 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
- Council Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters.
- Regulation 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
- Directive 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.
- Directive 97/66EC concerning the processing of personal data and the protection of privacy in the telecommunications sector
- 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

[1] LEXOLOGY, https://www.lexology.com/library/detail.aspx?g=27ae467a-e2ed-4efc-ba4d-16d74c95e661, last access 11/12/2017

amending Directive 2002/58/EC

- Helsinki Declaration in its latest version for the statement of the ethical principles for medical research involving human subjects, including research on identifiable human material and data

2.2.1 Principles, rights and obligations in data protection law

2.2.1.1 Definitions in data protection law

- **Personal data** – Art. 4 (1) GDPR provides a definition of personal data: any information relating to an identified or identifiable natural person. The definition is strongly connected to the notion of the data subject.
- **Genetic data** – Genetic data is a special type of personal data which relates to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.
- **Biometric data** – This type of personal data relates to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person.
- **Personal data concerning energy consumption** – Data concerning energy consumption relates to the consumption habits of a natural person. It should include all data pertaining to the consumption habits of a data subject which reveal information relating to the past, current or future energy consumption habits of the data subject.
- **Data subject** – Art 4 (1) in its definition of personal data also refers to the data subject (identified or identifiable natural person). Although exceptions exist, European data protection law protects the living being, should s/he be identified or identifiable through any information relating to her/him.
- **Data controller** – In the interpretation of the Regulation data controller is someone who *„alone or jointly with others determines the purposes and means of the processing of personal data"(*Art. 4 (7) GDPR*).* The definition is based to three separate building blocks: personal aspect (the data controller can be either a natural or legal person, however, according to the Working Party preference should be given to the latter), possibility of pluralistic control (referring to the joint controllership, whereas different parties act as controllers), and the elements which distinguish the controller from other actors (as the controller is able to determine the purposes and means of the processing).
- **Data processor** – according to art. 4 (8) processor is a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller. Compared with the controller, the processor is not able to determine the purposes and means of the processing operations.
- **Data processing** – 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.

2.2.1.2 Requirements of the processing of personal data and sensitive data

The objective of the Regulation is stated in art. 1 (2), *viz.* the protection of "the fundamental rights and freedoms of natural persons, and in particular their right to the protection of personal data." The main principles of data protection law must be applied in any instances of data processing where the GDPR is applicable.

- **Fairness, lawfulness and transparency of processing** – Data subjects should be able to know what information has been collected about them, the purpose of its use, who can access and use it. Users should also be informed about: how to gain access to information collected about them and how they may control who has access to it. To achieve this, the transparency of the data processing should be ensured. Data controllers should be clearly identified and be able to respond to requests of e.g. data subjects. Controllers must inform data subjects before the processing of their personal data about the main components of the processing (e.g. purpose of processing, identity and address of the controller, etc.).
- **Data minimisation and purpose limitation** – This fundamental principle of data protection is an expression coined by legal doctrine to refer to two key data protection principles, namely, the purpose limitation and the data quality principles. The purpose or use limitation, or purpose binding principle (Art. 6 (1) b) Directive) prohibits further processing which is incompatible with the original purpose(s) of the collection. The data minimisation principle must act as a general principle policy for any technological development: information systems and software shall be configured by minimising the processing of personal data. The purposes for which personal data are collected should be specified at the time of collection. In addition, the use of those data should be limited to those previously defined purposes.
- **Accuracy of data** – This principle implies that data must be adequate, up to date, relevant and not excessive for the purposes for which it is collected. Irrelevant data must not be collected and if it has been collected it must be discarded (Art. 6 (1) c) Directive). These key principles have been codified at constitutional level by art. 8 of the EU Charter, which states that personal data *"must be processed fairly for specific purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law".*
- **Storage limitation** – In principle data should be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which data were collected or for which they are further processed. Where possible data should be (pseudo-) anonymized.
- **Data security** – appropriate technical and organisational measures should be taken into consideration when personal data is processed in order to ensure the security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

2.2.1.3 Legitimate basis for processing

Personal data should be processed for one of the following reasons:

- Freely given, specific and informed consent of the data subject
- Performance of a contract to which data subject is a party
- Compliance with the legal duties of the controller
- Protection of the vital interests of the data subject
- Activity carried out in the public interest or exercise of official authority
- Legitimate interest pursued by the data controller

The NRG-5 project will process personal data based on the consent of the data subject (or their representative).Consent as a legal basis of processing personal data has three building blocks:

- The Data subject must give her/his consent freely, without undue pressure. The consent is freely given „if the data subject is able to exercise a real choice and there is no risk of deception, intimidation, coercion or significant negative consequences if he/she does not consent".

- The Data subject must be duly informed about the consequences of giving consent. To have sufficient information before giving consent data controller must provide easily accessible information in an easily understandable language.
- The consent must be specific, reasonably concrete, which relates to the reasonable expectations of an average data subject.

2.2.1.4 Processing of special categories of personal data (sensitive data)

Sensitive data is a category of data for which stricter requirements apply in terms of the legal base that is necessary. Medical data are considered as sensitive categories of data in consideration of the risks that their disclosure or misuse may procure. For this reason the legal regime is stricter and, in principle, prohibitive. Art. 9 (1) of the Regulation prohibits *"processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade-union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation."* In addition to the special protection measures outlined in Art. 9, the processing of medical data must abide by the fundamental principles of data protection, notably data minimisation, described above.

Given the definition of personal data, described in art. 4, the question arises as to which data should be considered medical data, whether they can be data about lifestyle or eating habits. According to the Article 29 Working Party, given the potential breadth of this class of data it is probably wise, the Working Party suggests, to consider all data contained in medical documentation, in electronic health records and in EHR systems, including administrative data, social security number, and date of admission to treatment or to hospital, as "sensitive personal data". When the processing of personal data relates to a person's health, such a processing activity requires special protection.

As mentioned above, the processing of personal data concerning health is, in principle, prohibited. However, the necessity exists in reality for sharing personal information in order to treat patients. Accordingly, certain derogations exist which permit processing of personal medical data. As these are derogations to the general prohibition rule, however, they must be construed in a narrow fashion and applied strictly. Next we highlight the most important derogations relating to NRG-5:

- ***Explicit consent:*** A derogation from the ban on the processing of personal medical data is allowed where "the data subject has given his explicit consent to the processing of those data". Consent is defined as "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her"(Art. 4 (11) GDPR). Consent can therefore constitute a justification for the processing of sensitive data. In order to be valid, consent must be "freely given" and contain "specific and informed indication of the data subject's wishes" (Art. 2 (h) Directive). Explicit consent must be traceable, thus a proof must be kept, and therefore it is given usually in written form.

- ***Additional purposes:*** The Regulation mentions (in art. 9 (2) j)) the purposes for archiving, scientific, historical or statistical purposes: these purposes shall be *„proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject."*

2.2.1.5 Rights and obligations of the data subject

As anticipated, the Data Protection Directive also recognises a number of subjective rights for data subjects such as the right to receive some information whenever data is collected, to access the data, to have data corrected, and to object to certain types of processing (Art. 12).

- **Right to be informed** – according to art. 12 GDPR the controller shall take appropriate measures to provide any information „to the data subject in a concise, transparent, intelligible

and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child. The information shall be provided in writing, or by other means, including, where appropriate, by electronic means."

- **Right to access** – *„the data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and where that is the case, access to the personal data…"* (Art. 15 GDPR) As the CJEU clarified in the Rijkeboer case, the right to access is necessary to enable the data subject to exercise his rights under art. 12 (b).
- **Right to rectification** – According to art. 16 *„the data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her. Taking into account the purposes of the processing, the data subject shall have the right to have incomplete personal data completed, including by means of providing a supplementary statement."*
- **Right to be forgotten** – The right to be forgotten (Art. 17 GDPR) will grant the right to the data subject to have his personal data erased: *"The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay" (*Art. 17 GDPR).
- **Right to data portability** – According to art. 20 *„the data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided."*
- **Right to object** – Art. 21 elaborates on the right to object: *„The data subject shall have the right to object, on grounds relating to his or her particular situation, at any time to processing of personal data concerning him or her."* Data subject has the right to object not only relating to his or her particular situation, but against profiling or direct marketing purposes as well.
- **Right to a judicial remedy and the right to receive compensation** – where the data subject considers that his or her rights under this Regulation have been infringed as a result of the processing of his or her personal data in non-compliance with this Regulation, he or she has the right to an effective judicial remedy and the right to receive compensation (Art. 79 GDPR).
- **The right to restriction of processing** (Art. 18 GDPR) – This right will be a new form of exercising data protection rights. Data subjects will be able to affect the extension of the data processing by claiming its restriction. Based on art. 18 (2) the conditions of restricted processing will be strict. Although it seems a technical solution, it will provide an interlocutory treatment of risk, while the data subjects decide the actual treatment.
- **The rights and freedoms of natural persons resulting from the processing of personal data** - Data Protection Impact Assessment (DPIA) (Art. 35 GDPR)- A DPIA is a process designed to describe the processing, assess its necessity and proportionality and help manage the risks to the rights and freedoms of natural persons resulting from the processing of personal data by assessing them and determining the measures to address them. A DPIA is only required when the processing is "*likely to result in a high risk to the rights and freedoms of natural persons*".

2.2.2 Transferring data across borders

The Data Protection Framework is also important in the regulation of cross border transfer of data. Furthermore the GDPR has an extended territorial scope. This means it applies to undertakings processing data relating to offer goods or services, or monitoring the behaviour of EU data subjects; even an undertaking outside of the EU, but targeting EU consumers will be subject to the new regulation. As Recital (9) GDPR underlines: *„Directive 95/46/EC… has not prevented*

fragmentation in the way data protection is implemented across the Union, legal uncertainty and a widespread public perception that there are significant risks for the protection of individuals..." EU data protection draws a distinction between transfers of data within the EU and transfers of data to third countries i.e. outside the EU.

2.2.2.1 Transfer within the EU

The general rule regarding the transfer of personal data across national borders is that it is permissible within the EU or with other countries outside EU that provide similar, adequate level of protection. Art. 1 (3) says *„the free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data."*

2.2.2.2 Transfer outside the EU

The principle provisions of the Directive were enacted not only in the EU but also in the countries of the European Economic Area (EEA) and most likely the enactment of the Regulation will be the same. Art. 44 contains a general principle for transfers: *„Any transfer of personal data which are undergoing processing or are intended for processing after transfer to a third country or to an international organization shall take place only if, subject to the other provisions of this Regulation, the conditions laid down in this Chapter are complied with by the controller and processor, including for onward transfers of personal data from the third country or an international organisation to another third country or to another international organisation. All provisions in this Chapter (transfers on the basis of an adequacy decision; transfers subject to appropriate safeguards; binding corporate rules; transfers or disclosures not authorised by Union law; derogations for specific situations; international cooperation for the protection of personal data) shall be applied in order to ensure that the level of protection of natural persons guaranteed by this Regulation is not undermined."*

Art. 45 GDPR requires a third country to ensure an adequate level of protection which is evaluated by the Commission. If the Commission has decided that the country in question has no adequate level of protection, *„a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available."* When neither the country provides adequate safeguards, nor the controller ensures the required safeguards, personal data can be transferred to third countries only if additional conditions are met.

2.3 Partner specific National Legislation

The consortium partners are fully aware of the national data protection authorities and will meet the requirements of their local data protection legislation:

Table 1: National Data Protection/Legislation Authorities

Italy
In Italy, personal data processing is based on and governed by Legislative Decree No. 196/2003, which contains the Italian Personal Data Protection Code (Code), which has implemented Directive 95/46/EC on data protection (Data Protection Directive) into the Italian legal system. In addition, the Italian Data Protection Authority (IDPA) is committed to issuing appropriate measures with regard to privacy and personal data protection matters. There are many areas directly regulated by the IDPA, including (but not limited to): Video surveillance, Biometric data processing, Health data processing, Data breach notifications, Bank information processing, E-health records, Data processing carried out by system administrators, Data processing for marketing and profiling purposes, Mobile payment and Cookies.
France

In France the key regulations relating to personal data are:

- Act No 78-17 on Information Technology, Data Files and Civil Liberties dated 6 January 1978 (DPA). This act was modified to implement Directive 95/46/EC on data protection (Data Protection Directive).
- Decree No 2005-1309 of 20 October 2005.

The DPA was substantially amended by Law No 2016-1321 for a Digital Republic dated 7 October 2016 (Digital Republic Law). In part the amendment was made to prepare for Regulation (EU) 679/2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), due to come into force on 25 May 2018.

The French Data Protection Authority (Commission Nationale de l' Informatique et des Libertés) (CNIL) supervises enforcement of the DPA and frequently issues decisions and guidelines on it. See box, Regulator details.

Germany

The German Parliament and the Federal Council have both approved the draft of a new Federal Data Protection Act (Bundestag printing matter 18/11325) in May 2017. The purpose of the draft is to align German data protection law to the European General Data Protection Regulation ("GDPR"), which will be applicable as of May 25, 2018. The new law is intended to replace the existing Federal Data Protection Act with an identically named new act.

The competence for complaints is split among different data protection supervisory authorities in Germany. Competent authorities can be identified according to the list provided under

https://www.bfdi.bund.de/bfdi_wiki/index.php/Aufsichtsbeh%C3%B6rden_und_Landesdatenschutzbeauftragte

Greece

In Greece, following the revision of the Greek Constitution in 2001, Article 9A was introduced to protect an individual's personal data against unlawful processing. It has also introduced for the first time the right to "informational disposition" as a distinct aspect of the right to privacy, which essentially means a person's right to know, control and decide when and whether his/her personal data are to be collected, processed, or used in any way.

Until the entry into force of Regulation (EU) 679/2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data in May 2018, the collection and use of personal data in Greece is regulated by the Data Protection Law (DPL) (Law 2472/1997), which transposed Directive 95/46/EC on data protection (Data Protection Directive) into domestic law.

There are also certain special laws that regulate specific sectors, including:

- Law 3471/2006. This regulates the collection and use of personal data in the context of electronic communications and transposed Directive 2002/58/EC on the protection of privacy in the electronic communications sector (E-Privacy Directive).
- Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data – amended by the Laws 2819/2000 and 2915/2000.
- Law 3917/2011. This regulates the retention of collected/processed personal data and transposed Directive 2006/24/EC on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks (Data Retention Directive).

Romania

In Romania, Directive 95/46/EC on data protection was implemented by Law No. 677/2001 on the protection of individuals with regard to the processing of personal data and the free movement of

such data (DPL).

Moreover, the following sectoral laws apply:

- Law No. 506/2004 on the processing of personal data and the protection of privacy in the electronic communications sector (Romanian E-Privacy Law), which implemented Directive 2002/58/EC on the protection of privacy in the electronic communications sector (E-Privacy Directive).
- Law No. 365/2002 on electronic commerce (Romanian E-commerce Law), which implemented Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Electronic Commerce Directive).

Spain

In Spain the Data Protection is governed by the "Agencia Española de Protección de Datos" Organic Law 15/1999, on 13th December, on the Protection of Individuals with regard to the Processing of Personal Data

The Regulation developing the Data Protection Act was approved by Royal Decree 1720/2007 of 21 December (Data Protection Regulations).

There are no sector-specific laws regulating the processing of personal data, but there are regulations that contain specific provisions on personal data processing (for example, Law 26/2006 on insurance and reinsurance intermediation). The most relevant regulations are the:

- Spanish Information Society Services Act (Law 34/2002 on information society services and e-commerce).
- Spanish General Telecommunications Act (Law 9/2014).

In addition, specific legal provisions apply to the processing of:

- Files regulated under the electoral regime legislation.
- Files used exclusively for statistical purposes and protected by legislation on public statistical functions.
- Files for storing data contained in personal classification reports referred to in the armed forces personnel legislation.
- Files derived from the Civil Registry and the Central Registry of Convicts and Fugitives.
- Files from video and audio recordings obtained by law enforcement agencies using video cameras.

Slovenia

In Slovenia, the Personal Data Protection Act (in Slovene language: Zakon o varstvu osebnih podatkov, ZVOP-1) was published in the Official Gazette of the Republic of Slovenia, No. 86/2004, as of 5 August 2004 and was partly annulled and corrected by the Information Commissioner Act, which was published in: Official Gazette of the Republic of Slovenia, No. 113/2005, as of 16 December 2005.

United Kingdom

The Information Commissioner's Office. Data Protection Act 1998: An Act to make new provision for the regulation of the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. [16th July 1998]

UK data protection law will change on 25 May 2018, when the EU General Data Protection Regulation takes effect, replacing the Data Protection Act 1998.

3 National Data Protection Authorities

All NRG-5 partners that handle personal data are aware of their National Data Protection Authorities and their data controllers will request the necessary permission before the start of relevant NRG-5's activities. A table summarizing the respective authority and partners involved in these activities is included below.

Table 2: Authorizations/declarations for personal data protection and the research with humans

Country	Organizations	Partner
IT	Garante per la Protezione dei Dati Personali, Italian DPA http://www.garanteprivacy.it/home_en	ENG ASM WIND3 EMOT
DE	Die Bundesbeauftragte für den Datenschutz und die Informationsfreiheit http://www.bfdi.bund.de/	RWTH
EL	Hellenic Data Protection Authority (HDPA), http://www.dpa.gr/	SILO OPT TEISTE
ES	Agencia Española de Protección de Datos (AEPD) https://www.agpd.es/	HIS VIS
FR	Commission nationale de l'informatique et des libertés (CNIL), https://www.cnil.fr/	TCS ENGIE UPMC
RO	Autoritatea Naţională de Supraveghere a Prelucrării Datelor cu Caracter Personal, http://www.dataprotection.ro/	RGAZ CRE
SL	Republika Slovenija Informacijski pooblaščenec, https://www.ip-rs.si/	JSI
UK	The Information Commissioner's Office, data protection register https://ico.org.uk	BT POPs

4 Data Collection, Storage, retention & destruction

This section describes in details the procedures to implemented with the DIATMIC project, along with the use case/pilots for data collection, storage, protection, retention and destruction,

4.1 Definitions

In this document, the following definitions apply:

- ***Anonymised***: also known as 'unidentified' in some Member State's national legislation. The sample or data does not contain information identifying a person, or the link to such information has been permanently severed.
- ***Pseudonymised***: also known as 'coded'. The sample or data is connected to a person, but this connection has been marked with an identifier that does not contain information identifying that person.
- ***Personal Data***: Data which may be used to identify a research participant. (Note: Although in some EU jurisdictions, personal data may also be used to describe human biosamples, in the context of this template, it relates to identifiable data only).

In many cases in the literature, terms such as ***'fully anonymous'*** or ***'strictly confidential'*** are used. However, NRG-5 has on purpose avoided such terms, as they are often impossible to define. Instead within NRG-5 we indicate how data will be anonymized (e.g. by removing all personal information that could directly identify an individual) and that whilst data will be made available to other researchers, confidentiality will be protected.

4.2 Procedures to be implemented by NRG-5 consortium

Overall, NRG-5 pilot experiments will be developed and operated in full consideration of data protection principles and will satisfy data protection requirements in accordance with EU directives and national implementations thereof. Personal data that will be captured, after consent from participants, will be processed according to the applicable data protection provisions, as presented in Chapter 2.

NRG-5's consortium guarantees that all legal provision of personal data and any location-aware services will be respected during all phases of the project. Also, NRG-5 is aware of existing technological measures necessary to minimize associated privacy risks. The key practices that NRG-5 will utilize are:

- The project will inform all participants of the research objectives and all aspects of the research that might reasonably be expected to influence their willingness to participate. NRG-5 will also explain all other aspects of the research about which the participants inquire. This will be done for participants asked to join an experiment so their decision will constitute an informed consent.
- NRG-5 will not intentionally deceive, mislead or withhold information of from the participants over the purpose and general nature of the experimentation and research.
- NRG-5 will collect in some experiments personal data about the participants and their behaviour. Consequently it will provide participants with any information to complete their understanding of the nature of research at the end of an experiment. The project will discuss with the participants their experience of the experiment in order to monitor any unforeseen negative side effects or misconceptions.

The consortium of NRG-5 can guarantee that all legal provisions of personal data and location-aware services will be respected during all phases of the project. There are various types of user related data, which are captured through different channels.

- NRG-5 will minimize the collection of and processing of personal data, and use anonymization techniques to remove the ability to identify individuals were possible depending on the nature of experiment.
- Where de-identifying is not possible or desired, NRG-5 will protect all data collected that can be attributed or traced to an individual. It will store such data only with consent.
- Based on consent, personalized data can be transferred into anonymized data records for wider dissemination after the project lifetime and for further exploitation.
- Use of secure data storage, encrypted transfer of data over the capturing channels, controlled and auditable access for different classes of data.
- Obscuring/removing user identities at the source of experimental data generation to prevent direct user tracing.
- Obscure location as much as possible and limit user tracking through correlation of de-personalized data based on its location.
- Personal data will be processed in compliance with the relevant legal regulations described in Chapter 2. Personal data will be collected on a strictly need-to-know basis, solely for the purposes of the NRG-5 project and will be destroyed when no longer needed for that purpose. Technical and operational measures will be implemented to ensure that users will be able to access, rectify, cancel and oppose processing and storage of their personal data.

4.2.1 Technological pathway

NRG-5 implements cryptography and other privacy-preserving state-of-the-art technologies/techniques, including

- **Anonymization of Data**: The consortium will explore cryptographic solutions and opportunities for separating any sensed or delivered data (e.g. information or alert from a human sensor) from human IDs. NRG-5 will be based on blockchains technology for automatically checking the integrity and trustworthiness of the information, but still treat data anonymously. This way the information on incidents coming from humans will be effectively anonymized, although traceability in case of intrusion is still possible, even though difficult in accordance to regulation (EU) 2016/679. This holds and covers all situations including prosumption data, data gathered through crowd-sensing, user location information for alerting purposes. NRG-5 will ensure that the inference of the data on the individual user is not possible at reasonable effort. This way the involved DSOs, acting as (energy prosumption) data controller will not need to worry about personal data protection. Additionally, delivering data for processing is legal if the purpose is the detection of security threats according to the (EU) 2016/679.
- **Privacy-Preserving Data Aggregation**: NRG-5 will implement online aggregation techniques of data from geographically co-located C&I prosumers and/or human sensors so that, utilities may have access to the aggregated (metering or other, e.g. energy network status related) information only, rather than to that of a single prosumer and/or human sensor. This way any privacy concerns concerning data from smart devices or crowd-sensing apps are eliminated. The experience in handling data from smart meters from the H2020 SUCCESS project (where multiple NRG-5's partners participate) will be exploited and relevant guidelines will be adopted
- **Automatic Video processing**: Surveillance video received by drones will be automatically processed, on the drones or on their gateways which is the closest possible to the data source (in compliance with data protection rules) processing point; thus personal data

privacy issues will be eliminated. Only in case an abnormal event or obstacle is detected, **authorized LEA** (i.e. legitimate authority) will be informed.

- **Data storage and processing as close to the source as possible**: User prosumption data will only be transferred to NRG-5 platform after anonymization and in-network aggregation has taken place. User location will be kept only on the system edge for alerting and advising in case of an incident while video processing (as already described) will occur automatically. Such data will be disclosed only for juridical use.

Furthermore, all partners will sign a specific contractual template to legally bind the individuals who can access the collected data. Each partner has been invited to have these confidentiality statements signed by the relevant team members.

4.3 Procedures to be implemented by NRG-5 pilots

The Ethics board will make sure that all NRG-5 pilots will present confidentiality statements to legally bind the individuals who can access collected data, as well as to ensure the upholding of ethics requirements on the participation of humans. Statements regarding the possible ethics issues arising from each sub-project shall be submitted. The template for these documents is presented in Appendix III – Pilot Confidentiality & Ethical Forms

4.3.1 Processing Without Electronic Means

In the case of having to process data without electronic means, e.g., in the case of paper-based questionnaires, or other similar procedures, NRG-5 will promote the following internal policies:

- The persons in charge of the processing shall be instructed in writing with regard to controlling and keeping, throughout the steps required for processing operations, records and documents containing personal data. For each person with access to data, a registry must be kept of the authorized persons with the time stamp of their last access to the database.
- If records and documents containing sensitive personal data are entrusted to the persons in charge of the processing for the latter to discharge the relevant tasks, said records and documents shall be kept and controlled by the persons in charge of the processing until they are returned so as to prevent unauthorized entities from accessing them; they shall be returned once the relevant tasks have been discharged.
- Access to archives containing sensitive data shall be controlled. The persons authorized to access said archives for whatever purpose after closing time shall be identified and registered. If an archive is not equipped with electronic devices for access control or is not placed under the surveillance of security staff, the persons accessing said archive shall have to be authorized in advance.

4.3.2 Security measures

Security measures for accessing transferred data could be applied during the NRG-5 pilots. The personal data of energy consumption research participants are pseudonymised. The list of pseudonyms must be kept separated from the data sources.

Each research must keep the data of participants in the NRG-5 experiments in a separate computer or hard disk, which can be accessed only by authorised personnel.

Pseudoanymisation is a technique that consists in replacing one attribute (typically the name) in a record, by another. Only a pseudonymous ID number is used to link individual-level data with participants' identities.

Only researchers who have signed the NRG-5 Confidentiality statement can have access to the codes (decryption key for pseudonymisation).

Whenever it is possible, the pseudonymised data stored in electronic device must be encrypted. This means that personal data of research participants are made unintelligible by transforming it into cipher text, thereby protecting it against unauthorized reading.

During the data acquisition phase, encryption is not possible. The personal data will be sent over secured transmission networks, such as FTP protocol or TLS 1.2.

4.3.3 Policy regarding data after the completion of the project

All personal data that cannot immediately be anonymized and is collected for evaluation purposes, will be deleted at the latest 1 month after the end of NRG-5 or 9 months after collection, whatever is earlier.

5 Individual Research participants recruitment

NRG-5 is a 5G PPP technological research project. As such, it focuses on the research and innovation in the 5G technological domains. Yet, as it runs pilots where individuals are indirectly involved and personal data could be collected, it is mandatory to define the procedures and methodology for identifying/recruit research participants directly in the NRG-5 project or indirectly in the NRG-5 pilots

This chapter described the NRG-5 basic principles covering the involvement of humans as study participants.

5.1 Rights of participants

Based on national and European legislation, NRG-5 considers the following participants' rights:

- All participants must be informed of the project's research goals - in the form of a research information sheet, in the appropriate language and, verbally if appropriate.
- Participation of persons in the NRG-5 pilots will be **entirely voluntary** and their informed consent will be requested in advance. They can refuse to answer any questions terminate or walk away from the research task at any time.
- Study participants will be provided with a detailed 'information sheets' describing the aims, methods and implications of the research and their rights.
- Research participants must be informed about the transfer of data and the security measures adopted.
- Research participants have a right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and where that is the case, access to the personal data.[2]
- Ethics approvals will be requested to the NRG-5 Ethics Board. Ethics approvals will be requested before the commencement of the part of the research raising ethics issues.

5.2 Criteria for identification of participants

Based on the experiments different groups of humans may be identified. They may equally cover:

- Different genders
- Different educational levels
- Different groups of ages
- Different types of profession (including unemployed)
- Different living environment (cities, town, villages, sea, mountains)
- Different culture and religion (or absence)
- Different nations
- Different geographical location

[2] Art. 15 GDPR, As the CJEU clarified in the Rijkeboer case, the right to access is necessary to enable the data subject to exercise his rights under art. 12 (b).

However, in all cases, the participants:

- Will be adults
- Will be able to apprehend the research information sheet details
- Will have a minimum level of intelligence that will enable them to understand their rights as research subjects.

5.3 Informed Consent Procedures for Data Handling

In order to make sure that research data can be made available for future reuse, it is important that consent for future reuse of the data by other researchers is sought from participants. Participants should be informed how research data from the trials (including personal data in some cases) will be stored, preserved and used in the long-term, and how confidentiality can be protected when needed. This section provides information of the procedures that NRG-5 will apply for the Informed Consent of participants for Data Handling.

5.3.1 Informed Consent Procedures

The following procedure will be followed for identification /recruitment of research participants via the NRG-5 pilots:

Step 1: Confidentiality Statements Forms by person performing the identification /recruitment

The initial step will be that the individual performing the identification/recruitment of research participants, either member of the NRG-5 Consortium or member of an pilot sign the relevant confidentiality statement. With this statement, s/he commit that no sensitive personal information or data will be disclosed anyhow. The template of the confidentiality Statement form for members of the NRG-5 consortium is available in Appendix II. Moreover, consortium members that will directly process data will also sign the Data Handling Form (Appendix IV)

Step 2: Identification of research participants

Asking for consent assumes that the owner of the data in question has given his/her prior consent to be contacted by the institution now seeking further consent to use the data. If this requirement is not met, it would be a breach of privacy to use the research participant's contact details in order to seek consent to further use of the data. Based on the nature of the experiment a call for volunteers will be published to relevant social media such as the NRG-5 web site, the NRG-5 twitter or facebook account, or the social media controlled by the consortia partners.

Step 3: Information Consent

The identified participants will be contacted by personnel that have already signed the confidentiality statements form (Annex II). The personnel will provide informed consent material in writing. Designated NRG-5 pilot staff will also inform in face to face meetings with potential participant about the scope and risks of the trial, and that participant is fully voluntary and can be aborted by the participant at any stage at his/her own discretion.

Step 4: Information Consent Certificate

After the person to be recruited in the research has been informed s/he will be asked to complete and sign the information consent certificate. Moreover, the investigator performing the research will include a statement that s/he confirms that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of his/her ability. After that he will sign the second page of

the Information Consent Certificate as stated in Appendix V. The information Consent Certificate will be signed twice and each participant will keep one copy.

Step 5: Information Consent Verification

Finally the Ethics Board will be assess and validate the informed consent procedures and the training procedures of the staff involved

5.4 Informed Consent Guidelines

Within NRG-5, informed consent material will be provided in writing. Designated trial staff will also inform in face to face meetings with potential participant about the scope and risks of the trial, and that participant is voluntary and can be aborted by the participant at any stage at his/her own discretion.

The Ethics Board will be the main body responsible for assessing and validating the procedures and methodologies to be used in project. This includes validating the informed consent procedures and the training procedures of the staff involved.

Research activities will be compliant with the Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC (OJ L158, 27/5/2014).

Within NRG-5 the following general Informed Consent guidelines will be assured. The participants will be provided with Informed Consent Form and Information Sheets, both will:

- be in a language and in terms fully understandable to them
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might be involved
- explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
- indicate how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently
- indicate what procedures will be implemented in the event of unexpected or incidental findings (in particular, if the participants have the right to know, or not to know, of any such findings).

It should be underlined that the highest level of anonymization will be used, whenever possible, to protect research participant's privacy, especially in case of AMI trial. It should also be noted that anonymized data are not considered to be personal data under Data Protection legislation and that anonymization requires proper de-identification in the sense that the research participant/data subject is not identifiable by reasonable means. However, full (unlinked) anonymisation deprives the participant of his/her right to withdraw his consent and claim the remaining material. Therefore, for this reason, data protection agencies are beginning to recommend that full anonymisation should be avoided.

The following general considerations regarding the consent forms should be taken into consideration by the test sites Local Ethics Committees.

1. Informed consent is a fundamental mechanism to ensure respect for people through provision of thoughtful consent for as a voluntary act. The procedures used in obtaining informed consent are designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "layman's language" (i.e. understandable by the people being asked to participate). The document is primarily thought of as a teaching tool, not as

a legal instrument. Additionally, jargon should be avoided and gesture (signing), diagrams and pictures should be used if appropriate. The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document will be revised when deficiencies are noted or when additional information will improve the consent process.

2. The researcher should be aware of the fact that the use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be, incorrectly, relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a participant.
3. Whenever possible, it should be arranged to obtain consent in good time before the beginning of the actual testing so that the person is not rushed at the last minute.
4. It should be ensured that auxiliary aids or services to assist communication are available where necessary.
5. Participants should be encouraged to ask questions and the supervisors should ensure that they have understood the explanations/clarifications provided.
6. It should be ensured that the participants may change their mind and withdraw at any moment without giving any reason and without any impact on them.
7. It is preferable to see the person on his/her own (unless a carer/interpreter needs to be present) but if she/he wishes partners, carers or family to be present, it should be made sure that they do not put undue pressure on the person either to consent or to withhold consent.
8. Potential participants shall also not be overwhelmed with unnecessary information.

In the informed consent the following information will be presented:

i. What the research is about
ii. Who is carrying out the research
iii. Any benefits to individuals or groups
iv. Any possible adverse effects
v. What the participants will have to do
vi. Length of the research
vii. Location of the research
viii. What the research findings will be used for
ix. What will happen to the results
x. Whether they will receive a summary of the results
xi. Confidentiality agreements
xii. Entitlement to service statement

5.5 Information Sheet

Though a template of the Information Sheet is provided in Appendix V – Information Sheet & Informed Consent Certificate, this section provides some additional information /explanation of the relevant fields. In general the form will be pre-filled by the investigator for each user to participate in one or more trials and as follows it should contain all this information:

5.5.1 Introduction

This section will briefly state who is the investigator (“Investigator”) and that he is inviting someone (“participant”) to participate in research which the Investigator is doing. He/she needs to inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if

they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime.

(Example: I am X, working for the Y organization. I am doing research on accessibility through electronic devices. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

5.5.2 Purpose of the research

This section should explain the research question **in lay terms** that will clarify rather than confuse. The investigators should use local and simplified words rather than scientific terms and professional jargon. In the explanation, s/he consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out 0about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

(Example: We want to find ways to make devices easy to access for people with disabilities through their preferences and needs. We believe that you can help us by telling us what you like and what are your needs when using digital devices. We want to learn about the way you use interactive technologies and the way you would like to use these technologies. We also want to know more about your experiences using technology because this knowledge might help us to learn how to improve auto configuration methods.)

5.5.3 Type of Research Intervention

This section should briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one hour interview).

5.5.4 Participant Selection

This section should indicate why the investigator has chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

(Example: You are being invited to take part in this research because we feel that your experience as a disabled person (or as an expert, or as carer) can contribute much to our understanding and knowledge of users' interaction with digital devices.)

> ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

5.5.5 Voluntary Participation

This section should indicate clearly that they can choose to participate or not. The investigators should state, **only if it is applicable**, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

> ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

5.5.6 Procedures

A. The investigator should provide a brief introduction to the format of the research study.

(Example: We are asking you to help us learn more about assistive technologies and their use among beneficiaries)

B. The investigator should explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion that may be sensitive or potentially cause embarrassment, inform the participant of this.

Example 1 (for focus group discussions)

Take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.

The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the assistive technologies and give you time to share your knowledge. The questions will be about assistive technology, how is it used, what people used, and what happens when used it.

We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.

The discussion will take place in [location], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 2 (for interviews)

Participation in an interview with [name of interviewer] or myself.

During the interview, I or another interviewer will sit down with you in a comfortable place at XXXX. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like

someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 3 (for questionnaire surveys)

You fill out a survey, which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys]. Or you may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.

If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)

5.5.7 Duration

This section should include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

> ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

5.5.8 Risks

Although there is no foreseen risk in NRG-5 research researchers should explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

Or if for example, the discussion is on opinions on government policies and community practices, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)

5.5.9 Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to provide an easy way to personalize electronic devices and services).

5.5.10 Reimbursements

The investigator should state clearly what s/he will not provide to the participants and reimbursement as a result of their participation. Small credits (e.g. a small gift) could be provided by the investigator (the Open Call applicant), which will not be covered by NRG-5. The credits (if any) should be determined before the interview.

Example: You will not be provided any incentive to take part in the research. However, we will give you [xxx as a gift] for your time (if applicable).

> ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your time lost? Do you have any other questions?*

5.5.11 Confidentiality

In this section, the investigators should explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, your clinician, etc.])

5.5.12 Certificate of Consent

This section is written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Example: I have been invited to participate in research about audiphones and hearing aids.

The following section is **mandatory:**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

If the participant is **illiterate** then the consent certificate will present the following format:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

5.5.13 Statement by the researcher/person taking consent

Finally the investigator includes a statement that s/he confirms that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of his/her ability.

6 References

[1] NRG-5 Consortium, “NRG-5 Description of Work,” Approved by EC on 18 May 2017

Appendix I – Individual Ethics & Confidentiality Statement Form

Individual Ethics & Confidentiality Statement

(NRG-5 Consortium Members)

Organization Name:.....

Title: .....

First name: .....

Family Name: .....

Passport/National ID number: .....

Email Address: .....

Telephone: .....

Home Address: .....

I, undersigned hereby confirm that I have read and fully understood the Ethics and Confidentiality policies of the NRG-5 project. I personally and formally commit to respect these rules and guidelines, as well as the respective European and National directives on personal data protection

I also commit to:

- Mitigate any identified risk that may breach these rules
- Ensure that access to stored personal data (if any) that is not made public is reserved only to those who have signed the present legal commitment
- Inform the NRG-5 consortium partners and/or the Ethical Board in the case I would identify any breach in the privacy and personal data protection policy.

Print name.....

Signature.....

Date .....

Day/Month/Year

Appendix II – Pilot Confidentiality & Ethical Forms

NRG-5 Pilot Confidentiality Statement Template

I, ***[name] [institution],***

- being aware of the purposes of the ***[name of the pilot location]*** pilot run under the 5GPPP NRG-5 (under the Horizon 2020 Framework Programme) (the "*Pilot*");
- having understood that personal information of and research information about participants in experiments (the "data set") can be exchanged only within the project with other researchers formally employed by the consortium, each of whom shall be bound by this statement ('*the participants*);
- having been informed about my legal obligations in terms of Personal Data Protection in research, and having had the possibility to ask questions in this respect to the NRG-5 coordinator and the partners in charge of NRG-5 pilots and legal aspects;
- been aware that I may be prosecuted for any breach of this statement that result in the unauthorized access, use, disclosure, modification, or destruction of the Data Set under the applicable national law of the country when I carry out the personal data processing activities;

Agree to

i. keep all personal information and research information shared with me confidential by not disclosing or sharing it in any form or format with anyone other than the *Participants*.

ii. employ all reasonable technical and organizational safeguards, including those safeguards taken to protect my own confidential information, to prevent any use, access or disclosure of the Data Set that would result in a breach of this Statement.

iii. protect all personal information stored on laptops or other personal devices, for instance using a password, or storing data related to NRG-5 pilots in a dedicated hard disk or computer, and ensure that containing personal information is transmitted over secure networks only.

iv. report, in writing, without unreasonable delay, but in no event later than seven days, to the Project Coordinator and Data Protection Manager of any incident of which I become aware relating to a breach of security and/or privacy of the data set including, but not limited to, any attempted or successful unauthorized use or disclosure of the data set.

v. cooperate with the NRG-5 consortium members in investigating data breaches and other unauthorised use of personal data.

vi. delete or in any case hide any personal information from the data set in publications disseminating the results of the project

vii. unless irreversibly anonymised, not use any personal and research information in any form or format after completion of the project.

Done in two copies, of which one is for the researcher and one for the NRG-5 Consortium.

(Print Name)	(Signature)	(Date)

NRG-5 Pilot Ethics Clearance Statement Template

Name of Pilot (location):	
Name of Pilot Representative	
Purpose of the data collection and processing	
Does the data collection, generation and processing involve:	Human participation for data collection**:** ☐ **No** ☐ **Yes** If yes please provide Information Sheet and Informed Consent Certificate from participants Personal Data ☐ **No** ☐ **Yes** Sensitive Personal Data ☐ **No** ☐ **Yes**
Does the project use connection to existing database?	☐ **No** ☐ **Yes** If yes please provide details (name, purpose, means...)
Existing data being re-used?	☐ **No** ☐ **Yes**
Any ethical or legal issues that can have an impact on data sharing?	☐ **No** ☐ **Yes** please provide details (e.g. pseudo anonymization, data transfer between countries,

(Print Name)	(Signature)	(Date)

Appendix III – Data Handling Informed Consent

Data Handling Information Consent Form

	Yes
Please tick the appropriate boxes	
Taking Part	
I have read and understood the project information sheet dated DD/MM/YYYY.	☐
I have been given the opportunity to ask questions about the project.	☐
I agree to take part in the project. Taking part in the project will include being interviewed and recorded (audio or video).	☐
I understand that my taking part is voluntary; I can withdraw from the study at any time and I do not have to give any reasons for why I no longer want to take part.	☐
Use of the information I provide for this project only	
I understand my personal details such as phone number and address will not be revealed to people outside the project.	☐
I understand that anonymized data may be quoted in publications, reports, web pages, and other research outputs.	☐
*Please choose **one** of the following two options:*	
I would like my real name used in the above	☐
I would **not** like my real name to be used in the above.	☐
Use of the information I provide beyond this project	
I agree for the data I provide to be archived at the data repository selected by NRG-5	☐
I understand that other authenticated researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.	☐
I understand that other authenticated researchers may use my words in publications, reports, web pages, and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.	☐
Consent Certification	
I agree to assign the copyright I hold in any materials related to this project to *[name of researcher]*.	☐

_____		_____	_____
Name of participant	[printed]	Signature	Date
_____		_____	_____
Researcher	[printed]	Signature	Date

Appendix IV – Informed Consent Certificate

Informed Consent Certificate

I, undersigned ***[name] [date and place of birth – natural person; registry number – legal entities] [contact details] [if representing a minor: her/his name, date of birth, etc.]***, hereby give my consent to take part in the research carried out by the NRG-5 Research Consortium.

1. I have been informed that the ***[name of the pilot/use case]*** pilot is part of a research project currently run under the H2020 NRG-5 project. The co-ordinator of the pilot is ***[name] [registry number – legal entities] [contact details]***, who might be contacted with regard to any question regarding my participation.
2. I have been informed about the purposes of the project. I have had all my questions answered to my satisfaction.
3. My participation in the research will include ***[describe in detail]*** .....
4. Information obtained during the research will be used for ***[describe in detail]*** .....
5. My personal data will be made available only to the members of the Consortium and possibly the NRG-5 Consortium.
6. I understand that any further use of this information will require my separate consent.
7. I require not to be identifiable in any research results.
8. I understand that I will not be paid for my participation.
9. I give this consent fully informed, freely and voluntarily and I understand that I am free to withdraw my consent and discontinue my participation at anytime without any negative consequences.
10. The relevant laws of ***[country]*** shall apply.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

[or in case of is illiterate participant: I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.]

Print name of witness.....

Signature of witness .....

Date .....

Day/month/year

Page 1/2

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. .....
2. .....
3. .....
4. .....

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Certificate has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

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Information Sheet Template

Introduction

Briefly state who you are and that you are inviting them to participate in research which you are doing.

Purpose of the research

Explain the research question in lay terms that will clarify rather than confuse.

Type of Research Intervention

Briefly state the type of intervention that will be undertaken.

Participant Selection

Indicate why you have chosen this person to participate in this research.

Voluntary Participation

Indicate clearly that they can choose to participate or not.

Procedures

i. Provide a brief introduction to the format of the research study.
ii. Explain the type of questions that the participants are likely to be asked in focus groups, interviews, or surveys.
iii. Clarify the type of personal data to be gathered, e.g. biometric, and the procedures by which they will be gathered.

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

Risks

Researchers should explain and describe any anticipated or possible risks.

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

Reimbursements

State clearly what you will provide the participants with as a result of their participation. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

Confidentiality

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality.

Certificate of Consent

Signed by both parties