



Deliverable 5.1

Set of guidelines

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Introduction

In the framework of AAL Programme, projects are focused on developing ICT products/services dedicated to support active aging. AAL systems/solutions must meet high ethical standards and ensure compliance with the different national laws of all the countries in which the project have to be tested and marketed.

From an ethical point of view, each AAL project must monitor both the modality of implementation of the project that the project's results, hence, ethical issues must be taken in account in all phases of the project: the conception of services, the users involvement, the experimentation, the validation and the marketing.

The main ethical concerns that are involved in the AAL framework are privacy, control of personal data, confidentiality, autonomy and dignity, and such an issues must be explored in relation with the use of innovative ICT solutions that can be complex to manage for final users and caregivers, if they do not have an appropriate technological awareness.

This document explains how the NOAH AAL project intends to handle the ethical and legal issues related to users' involvement, information-consents, installation and test activities.

In Sec.1 the basic concepts dealing with the ethical criteria, in the context of NOAH project, are presented.

Sec.2 the legal references related to the experimentation activity involving users are briefly described.

In Sec.3 a draft of the "informed-consent form" adopted in the NOAH project is proposed.

Finally, some conclusions are drawn.

1 – Ethical issues for the NOAH project

NOAH (NOt Alone at Home) project addresses the theme of the exploiting ICT to promote independent life of older adults living alone, by empowering them in daily life activity self-management, by providing them with a more effective connection to their supporting networks (relatives, friends, caregivers) and by augmenting their safety.

Project work methodology approach foresees the adoption of an active contribution of users, formal/informal caregivers, stakeholders, in order to devise the services, according to a Co-Creative paradigm, also for ensure that issues as autonomy and dignity of persons are taken in account, already in the design phase.

Heterogeneous work groups will be engaged in devising and assessment of NOAH services in order to evaluate that project activities and users' involvement are compatible with the principles and values of the elderly people and their families.

The control of personal data and the confidentiality issues are ensured by the cloud-based architecture of the NOAH AAL system. Data are addressed by means of intrinsically safe standard internet communication protocol to a professional cloud service. Furthermore, information could be properly anonymized and encrypted (if needed).

A key role in the handling of privacy issues is played by a specific information-consents (explained with more details in sec.3).

All partners of the NOAH project must respect the ethical guidelines set out in this document, i.e. that:

- the identity of users to third parties will be protected
- the data are collected and stored in a secure and anonymized database
- all the European and national regulations will be followed
- all the parties involved (end users and informal caregivers) are fully informed of what's involvement in the trial involves

2 – Legal references

NOAH project will take in account all the main relevant ethical issues and will correspond to the fundamental ethical principles in the use of personal data and the involvement of users in testing activities, according with the widely accepted policies and regulations.

Despite the diversity of specific national laws, all EU country agree on a main theme: user participation must be voluntary and must be implemented ensuring the highest possible safety of user.

Given this facts and other base principles universally recognized as fundamental ethical issues in the field of scientific experimentation (as, for example: Nuremberg Code, Helsinki Declaration, Charter on the Fundamental Human Rights in the EU, UNESCO Declaration on the responsibilities of the present Generations Towards the Future Generations, Ethics and EU funded research Council Decision 1513/2002/EC on FP6.), NOAH project has defined a set of ethical criteria to drive the project work methodology:

- User's voluntary consent will be ensured by the means of a “informed-consent form”. Voluntary participation implies that the user must not be forced and joined the project on its own initiative.
- Experimentation is aimed at finding solution dedicated to improving the quality of life of users. Testing activities are proportionate to the objectives to be achieved: there are no risks of death or serious injury to users. The project will ensure that the experimentation will be conducted so as not to damage the users (both physically and psychologically).
- All the people involved in the project will be professional and qualified operators.
- If during the implementation of the project unforeseen ethical concerns arise, it will be the responsibility of the project partners to bring the matter to the attention of the Project Coordinator for an ethics review: the theme in question will be analyzed and, if needed, it will be identified the appropriate solution to avoid any kind of risk to the user.
- Users can leave the experiment at any time and testing will be interrupted, if there are reason to believe that the continuation would violate the principles listed above.

In addition to the international standard and base principles that are embedded in the NOAH list of ethical criteria, partners will act in accordance with the EU and national laws.

In particular, the main reference is EU law regard the “Protection of personal data” (<http://ec.europa.eu/justice/data-protection/>). In January 2012, the European Commission proposed a comprehensive reform of data protection rules in the EU that has been constantly updated over the past years (last update 14-11-2016), in order to give citizens back control over of their personal data, and to simplify the regulatory environment for business.

Furthermore, as regards the definition of the working method, NOAH partners will need to consider the following normative references:

Italy	Directive 95/46/EC, entered into force on the 1st. of January 2004 – Legislative Decree n. 196/2003 – Decision of the Responsible Authority on Privacy (Garante) n. 52/2008 – and related general authorizations: n. 2/2013, n. 8/2013 and n. 9/2013. People involved in the study will have to sign informative and agreement forms related to their participation in the research and the utilization of data (<i>Nota Informativa al trattamento dei dati personali e sensibili; Consenso Informato</i>)
Romania	Law 667/2001 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (L nr. 677 published in M.Of. nr. 790 on 12/12/2001).
Belgium	2001 Royal Decree implementing the Privacy Act, on the occasion of the transposition of European Directive 95/46/EC into the Privacy Act. In 2003, a second implementing decree established the way the sector committees work.

Finally, the EU has recently approved the Regulation (EU) 2016/679 General Data Protection Regulation (GDPR) — “Protection of natural persons with regard to the processing of personal data and the free movement of such data”, which is expected to apply from May 2018. At the time of writing, however, practical implementation of GDPR within local and National regulatory

frameworks is still to be completed. The NOAH project will monitor such process and take into account related recommendations as well.

3 – Informed-consent

The “Informed-consent” is a process, devised in healthcare framework, in order to obtain and manage permission before an intervention on a person. This tool has become a key element in the management of personal information in respect of the guarantee of confidentiality and privacy.

The consent can be said "informed" if it was given on the basis of a clear assessment and allowing a proper understanding of the implications and consequences of an action. An appropriate informed consent is rooted in respect for human dignity. To give informed consent, a person must have adequate reasoning faculties and be in possession of all relevant facts.

Partners of NOAH project involved in pilot sites experimentation (in Italy, Romania and Belgium) are working to develop a specific NOAH informed-consent form to be submitted to users selected for the test implementation.

Currently, the document is under development and it has to be compliant to Italian, Romanian and Belgian laws.

An extract of the draft is showed above:

*“... the **NOAH** project aims to inform that the processing of your data will be done in accordance with (national law references). In particular, we point out that the data will be used only in the framework of the project. For each person who adheres to the research project will be assigned a code that will always replace surname and name of the person himself. The observation period has a duration of ___ months in the initial stage and will be continued according to both sides agreements.*”

We inform you that the owner of data processing is (NOAH partner involved in the pilots' management).

With the commitment to the project you are willing to give the following information:

- Personal data (surname, first name, address ...);*
- The monitoring of your position/movement at home (this activity does not qualify as geolocation).*

Data collected are used in only for the NOAH project; dissemination activities are carried out in an aggregate and statistical form, in no case can be traced back to the person who has joined the project.

According to (national law references) you have the following rights:

1. the right to obtain confirmation as to whether or not personal data concerning him/her, even if not yet recorded, and their communication in intelligible form.

2. the right to obtain information about:

- a) the origin of personal data;*
- b) the purposes and methods of treatment;*
- c) the logic applied in case of processing with the aid of electronic instruments;*
- d) the identity of the owner, manager and the legal representative*
- e) subjects or categories of persons to whom the data may be communicated or who can learn about them as appointed representative in the State, managers or agents.*

3. the right to:

- a) updating, rectification or, when interested, integration of data;*

b) the cancellation, anonymization or blocking of data processed unlawfully, including data whose retention is unnecessary for the purposes for which the data were collected or subsequently processed;

c) certification that the operations in letters a) and b) have been notified, also as regards their content, to those to whom the data were communicated or disclosed, except if this requirement it proves impossible or involves a manifestly disproportionate to the protected right.

4. the right to oppose, in whole or in part:

a) for legitimate reasons the processing of personal data, pertinent for collection purposes;

b) to the processing of personal data for purposes of sending advertising materials or direct selling or for carrying out market research or commercial communication..."

Conclusion

In AAL programme a great importance is given to ethical issues and legal aspects. NOAH project take in account these aspects during all phases of the project to better respond to user needs and respect their rights.

By defining a set of ethical criteria and adopting a specific form for informed consent, the NOAH project is able to adequately respond to all the AAL programme requirements.

How is the issue of informed consent handled?

Informed consent will be managed by the project partners directly involved in the recruitment of users and in the management of the pilot testing. The user, duly informed about the purpose of the project and the effects on his life deriving of his involvement, must sign a form specially prepared.

- *What procedures does the proposal have to preserve the dignity, autonomy and values (human and professional) of the end-users?*

NOAH project is aimed at improving the quality of life of users and support their autonomy. The trial does not include activities that may threaten the dignity or integrity of the users. All technological procedures to ensure their privacy and confidentiality will be taken (data anonymization). Users will be duly informed about what is involved in participating in the project and will be involved in the definition of services in order to ensure that monitoring activities do not adversely affect their values.

- *If the proposal includes informal carers (e.g. relatives, friends or volunteers) in the project or in the planned service-model, what procedures exist for dealing with ethical issues in this relationship?*

The project will take a co-creative approach involving in the definition of needs (besides elderly users) formal and informal caregivers, in order to contributing to ideation and providing feedback on service concepts. In addition, end users will always be informed of such persons may have access to information related to monitoring activities, also in the case of relatives or others informal caregiver.

- *If the proposal includes technology-enabled concepts for confidential communication between the older person and informal and formal carers, service providers and authorities – what procedures are planned for safeguarding the right to privacy, self-determination and other ethical issues in this communication?*

The electronic communications infrastructure developed within the NOAH project involves the use of anonymization techniques and adoption of secure protocol of communication. User data are stored on cloud-based platforms which guarantee excellent levels of security. Users can at any time request the cancellation of their data should they decide to get out of the trial.

- *What "exit" strategy for the end-users involved in the project does the proposal have (in terms of end-users leaving the project during its implementation and after the project's end)?*

As declared in the list of ethical criteria, each user can leave the experiment at any time and testing it will be interrupted mean any time if there was reason to believe that the continuation would violate the principles listed above. Physical devices provided at the end user in the context of NOAH pilot remain the property of the end user, unless the user asks for having them removed by the pilot team.

- *How are the ethical dimensions of the solution targeted in the proposal taken into account? (Brief description of distributive ethics, sustainability et.al.)*

From a technological point of view, the solutions to be adopted in the NOAH project will be developed by maximizing the use of standard and mainstream technologies (for both hardware sensors that for the software infrastructure) in order to contain, as much as possible, the implementation and management costs. In the context of elderly home care, to have economic solution is the best guarantee of equity and sustainability.

