



DELIVERABLE

D7.8 – Template for ethical approval and informed consent

Project Acronym: UNCAP

Grant Agreement number: 643555

Project Title: Ubiquitous iNteroperable Care for Ageing People

Revision: 1.0

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1. Revision history and statement of originality

1.1. Revision history

Rev	Date	Author	Organization	Description
0.1	07/10/2015	Elisa Morganti	FBK	First Draft
0.2	15/10/2015	Nicola Pace	FBK	V0.2
0.3	20/10/2015	Francesco Tessarolo	FBK	V0.3
0.4	22/10/2015	Elisa Morganti	FBK	First consolidated version V1.0
0.5	28/10/2015	Elisa Morganti	FBK	Revision
1.0	30/10/2015	Giuseppe Conti	TRILOGIS	Final revision

1.2. Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

2. List of references

Number	Full Reference
[1]	European Commission, Directorate General for Health and Consumers (2010). Guidelines on Medical Devices. Clinical Investigations: Serious Adverse Event Reporting Under Directives 90/385/EEC and 93/42/EEC. Available online at: http://ec.europa.eu/health/medical-devices/files/meddev/2_7_3_en.pdf
[2]	European Commission, Enterprise and Industry Directorate General (2009). Guidelines on Medical Devices. Clinical Evaluation: a Guide for Manufacturers and Notified Bodies. Available online at: http://ec.europa.eu/health/medical-devices/files/meddev/2_7_1rev_3_en.pdf
[3]	European Commission, Directorate General for Health and Consumers (2010). Guidelines on Clinical Investigation: a Guide for Manufacturers and Notified Bodies. Available online at: http://ec.europa.eu/health/medical-devices/files/meddev/2_7_4_en.pdf
[4]	Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC). Available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:en:PDF
[5]	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and further amendments. Available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF
[6]	EN ISO 14155:2011. Clinical investigation of medical devices for human subjects - Good clinical practice. Available online at: http://www.iso.org/iso/catalogue_detail?csnumber=45557
[7]	European Directive 95/46/EE of the European Parliament and of the Council of 24 October 1995. Available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

4. Table of Acronyms

Acronym	Description
AD	<i>Alzheimer Disease</i>
ADL	<i>Activities of Daily Living</i>
CHA	<i>Community health</i>
CHESS	<i>Changes in Health, End-stage disease and Signs and Symptoms</i>
CI	<i>Cognitive Impairment or Clinical Investigation</i>
CIP	<i>Clinical Investigation Plan</i>
CPS	<i>Cognitive Performance Scale</i>
CRF	<i>Case Report Form</i>
DCF	<i>Data Collection Form</i>
DRS	<i>Depression Rating Scale</i>
EEA	<i>European Economic Area</i>
EUDAMED	<i>European Database on Medical Devices</i>
FTD	<i>Fronto-Temporal Dementia</i>
GMDN	<i>Global Medical Device Nomenclature</i>
GP	<i>General Practitioner</i>
HC	<i>Home Care</i>
IADL	<i>Instrumental Activities of Daily Living</i>
IB	<i>Information Brochure</i>
ID	<i>Identity</i>
LTCF	<i>Long term care facility</i>
MAPLe	<i>Methods for Assigning Priority Levels</i>
MCI	<i>Mild Cognitive Impairment</i>
NCA	<i>National Competent Authority</i>
NCD	<i>Neuro Cognitive Disease</i>
PHP	<i>Personal Health Profile</i>



RUG	<i>Resource Utilization Groups</i>
SADE	<i>Serious Adverse Device Effect</i>
SAE	<i>Serious Adverse Events</i>
TBI	<i>Traumatic Brain Injury</i>



5. Executive Abstract

This document is a structured template for the design of clinical investigations in the form of randomized controlled pilot study. This document will help promoters of the clinical investigation¹ comply with ethical regulations and through a detailed description of the documents required to formally achieve clearance by each local ethical committee.

In order to start a clinical investigation on human subjects that requires use of a medical device without CE mark, each promoter should:

- **Obtain approval from the local ethical committee.**
- **Notify the National Competent Authority.**

Moreover, the pilot responsible (principal investigator of the study) should obtain the informed consent from the involved subjects.

Although in UNCAP, several pilot studies will be conducted, one for each pilot site, according to specific UNCAP configuration and setting (depending on the requirement of each pilot site), all pilot studies will share the same research question, primary outcomes and evaluation tools. In particular, each pilot site will define their treatment procedures, study procedures (adhering to the proposed timeline), the features - among the many available through UNCAP- to be adopted and will customise collection tools according to their implementation plan, local procedures and rules.

This way, UNCAP will be evaluated at pilot level by using only those features required by each given set of requirements, while allowing an ex-post meta-analysis of results coming from the various pilot studies. Data collection, sharing and analysis will always be conducted in full respect of dignity, privacy and confidentiality of personal information of the involved subjects.

¹ In UNCAP, the promoters of the clinical investigations are either the *care institutions* themselves or *the technical supporting partners*, depending of each pilot site formal engagement within the project (i.e. respectively as full

6. Table of Content

1. Revision history and statement of originality	2
1.1. Revision history	2
1.2. Statement of originality	2
2. List of references	3
4. Table of Acronyms	4
5. Executive Abstract	6
6. Table of Content	7
7. Template for ethical approval	9
7.1. Study protocol.....	9
7.1.1. Study title	9
7.1.2. Start and end date.....	9
7.1.3. Promoter	9
7.1.4. Principal investigator	9
7.1.5. Background and rationale	9
7.1.6. Objective.....	11
7.1.7. Study design.....	11
7.1.8. Research question	11
7.1.9. Target population and setting	11
7.1.10. Sample size	11
7.1.11. Inclusion criteria	12
7.1.12. Exclusion criteria	12
7.1.13. Randomization procedures	12
7.1.14. Treatments procedure	13
7.1.15. Study procedure	14
7.1.16. Criteria for discontinuing subjects	14
7.1.17. Data handling.....	15
7.1.18. Outcome variables	15
7.1.19. Statistical analysis	16
7.1.20. Subject's economic implications	16
7.1.21. Management and notification of serious adverse events	16
7.1.22. Funding	17
7.1.23. Result handling and diffusion	17
7.2. Data Collection Forms.....	17
8. Informed consent	18
8.1. Subject information and informed consent.....	18
9. Other documents	18
9.1.1. Insurance for the principal investigator	18
9.1.2. Declaration of additional cost	18
9.1.3. Notification to the national health authority	18
9.1.4. Notification to the Data Protection Authority	19



9.1.5. Investigator's Brochure (IB) The investigator's brochure should include:	19
9.1.6. CV of principal investigator	19
9.1.7. Labelling	20
10. Conclusions.....	21
ANNEX I – Notification form	22
ANNEX II - Matching sheet	27
ANNEX III – Data collection form	28
ANNEX IV – Caregiver Diary.....	29
ANNEX V – Adverse event reporting form	30
ANNEX VI – Subject's information	31
ANNEX VII – Informed consent	38
ANNEX VIII – Atl@nte scales definition	40

7. Template for ethical approval

The following sections detail the various parts of the template that has been edited to allow requesting ethical approval for each pilot site.

7.1. Study protocol

7.1.1. Study title

A pilot study to assess clinical and organizational impact of the UNCAP technology.

7.1.2. Start and end date

Provisional starting date: 1st April 2016

Expected study length: 15 months

7.1.3. Promoter

[A "promoter" or "sponsor" of the clinical investigation is defined as "a person (or entity) who takes responsibility for and who initiates a clinical investigation]

[This should be either 1) the care institution to which the subjects refer for the management of patients suffering of CI, or 2) the technical partner supporting them].

7.1.4. Principal investigator

[The person who is responsible of scientific aspects of the clinical investigation]

7.1.5. Background and rationale

It is well known that aging is directly related to increase in cognitive impairments. Dementia, generally meant as a degenerative decline of cognitive functions, for instance, mainly affects people aged 60+ (approx. 15% of people aged 80-84 and 32.4%-48.8% at 95). In 2006, the number of people affected by various forms of dementia was estimated at 7.3 mill. (1.4% of the population). At the current aging trend, this number will double every 20years.

UNCAP starts from the aforementioned outlook by specifically addressing aging people with Cognitive Impairments (CI). Dealing with these users is a complex and evolving task particularly in the case of ageing dementia and other degenerative diseases were the natural history of CI is one of progressive decline due to gradual deterioration of subjects' cognitive, physical, and social functions. UNCAP fosters -in line with modern literature non-pharmacologic approaches as an appropriate initial strategy able to help subject maintain dignity, autonomy, and a qualitative good level of life for a longer period. Subjects with mild or moderate CI can live and perform best in an environment that is safe, calm, and predictable.

UNCAP leverages on ICT technologies to create supporting technologies that can facilitate reduction of environmental stressors, lower agitation and anxiety of the subject. These interventions can be as simple as redirecting and refocusing the subject, increasing social interaction, establishing regular habits, eliminating sources of conflict and frustration, (also through integration with home automotive aids), providing rewards for successes (also promoting forms of social sharing) and assisting



subject in his/her orientation at home or outside through “transparent” monitoring of their actions (in terms of physical movements) and physiological parameters.

The capability to monitor physical movements and clinical parameter is also used by UNCAP to promote exercise and training, both at physical, emotional and cognitive level, further helping CI subjects face and delay deficits.

Furthermore, UNCAP sustains communication and language skills by increasing subjects’ social interactions, by offering opportunities of social life also based on social networks that can help share activities and experiences, stimulate gaming, etc. This integrated approach increases independence and it allows the creation of very personalised training programs, which account for social interactions and experience sharing. The increased degree of autonomy is also beneficial to family caregivers, whose reduced feelings of burden may in turn help reduce well-known forms of depression. In addition, UNCAP contributes to improvement of the care process and awareness, and the quality of life of the family.

Technology is used to pursue a behavioural intervention strategy with the goal of minimising (if not removing) any triggers of behavioural problems, while providing at the same time comforting stimulation. Literature shows how with this type of treatment, changes in the environment can be made to help minimize memory, visual-perceptual, or orientation difficulties. Research has shown that behavioural strategies can also help deal with other problems such as impulsivity, wandering, poor initiation, and problems with communication. The goal of UNCAP is to help subjects benefit –as much as possible- from a regular routine in their day-to-day activities to help them feel comfortable with a clear, structured schedule.

However, since the subjects cognitive functioning is declining progressively, the effects of interventions must be monitored continually and adjustments made over time in response to new emerging behaviours. For this reason UNCAP provides effective solution through physical/cognitive assessment tools, remote-monitoring features and through indoor/outdoor tracking capability.

In practice, UNCAP will deliver a product suite comprising of a low-cost Android-based unit, called the “UNCAP BOX”, to be connected to standard TV sets, which collects data coming from different indoor and outdoor localisation technologies (e.g. sensor flooring, camera-based detection system, etc.) as well as from sensors (e.g. measuring vital parameters, environmental temperature etc.), and makes them available –via secure communication channels- to the “UNCAP CLOUD”. The UNCAP BOX will also be used as the interface for end users, caregivers and family members who will be able to communicate (also via video conference), exchange health data (via HL7 standard), access assessment of the subjects conditions (through InterRAI™ assessment tools and methodology, Atl@nte suite) as well as to place emergency calls. Most interestingly, the UNCAP BOX will support interoperable communication, via KNX open protocol, with building automation systems which can be not only controlled by UNCAP services, but also be used as further feedback channel (e.g. by flashing lights to enforce a reminder, or turning lights on to a given room the user wants to reach). The UNCAP BOX will be also complemented by an App (UNCAP App also referred to as “UNCApp”) for smartphones or tablets, to provide a further convenient portable access to UNCAP services as well as to allow for access to selected UNCAP services in online as well as offline mode or from locations that are not instrumented with UNCAP infrastructure.



7.1.6. Objective

The objective of the investigation is to perform a pilot study to assess safety, clinical effectiveness and organizational impact of UNCAP when applied to the care of elderly people with mild and moderate cognitive impairments.

7.1.7. Study design

One of the main characteristics of UNCAP is its modularity that allows the customization of UNCAP features according to the real setting. In the framework of the research project, UNCAP will be tested in three different settings:

- nursing home (high-tech/long-term care),
- home care (low-tech/high-tech care),
- community health facilities (high-tech care).

A total of 11 pilot sites in Europe (including FYROM) are involved in the project. Each of the pilots will implement a subset of features chosen according to the specific application scenario and environment.

The modularity and adaptability of UNCAP to different scenarios reflects the complexity of the clinical investigation to assess the effectiveness of UNCAP. Several pilot studies will be conducted separately at each pilot site according to specific UNCAP configuration and setting. Nevertheless all pilot will share the same research question, with a common set of primary outcomes and evaluation tools.

This way UNCAP will be evaluated at pilot level by using the features required for the specific setting, while allowing an *a posteriori* meta-analysis of results coming from the various pilot studies. Data sharing and analysis will always be conducted in the respect of the dignity, privacy and confidentiality of personal information of the involved subjects.

The investigation will be conducted as a controlled prospective parallel study.

7.1.8. Research question

What is the safety, effectiveness and impact of the locally implemented UNCAP features compared to the current local standard of care?

7.1.9. Target population and setting

Ageing people with mild and moderate cognitive impairments

- Living in a nursing home.
- Living at home.
- Joining a community health facilities.

7.1.10. Sample size

___ subjects in the control group *[insert the expected number of subjects to be enrolled in the study and managed according to the local standard of care]*

___ subjects in the test group *[insert the expected number of subjects to be enrolled in the study and managed with UNCAP]*

7.1.11. Inclusion criteria

Note:

Inclusion/exclusion criteria are indicative and they needs to be validated by the Medical Committee by the end of November

Specific inclusion criteria include subjects with mild and moderate Neuro Cognitive Disorder (NCD) caused by:

- AD (Alzheimer Disease),
- FTD (Fronto-Temporal Dementia),
- Lewy body disease,
- Vascular disease,
- TBI (Traumatic Brain Injury).

Atl@nte CPS score will be used to select mild and moderate NCD conditions (ANNEX VIII).

7.1.12. Exclusion criteria

The following exclusion criteria have been identified for all the pilots. Those subjects meeting the following conditions will be dropped out from the study.

- Major NCD (dementia).
- Mild NCD due to:
 - Drug abuse due to presence of comorbidities with Personality Disorder not compatible with this studio,
 - HIV infection, since medical complications are not manageable.
- Subjects with depression symptoms due to probability of (minor/major) progressive deterioration/decline.
- Presence of psychiatric comorbidity.
- Presence of behavioural disorders (difficult research management).
- Subjects with severe functional or sensorial impairments (e.g. blind or tetraplegic subjects), that could jeopardize the use of the technological devices tested in the project.
- Subjects enrolled in a pilot study showing quick progress of the MCI toward more severe forms of cognitive diseases or other diseases that imply loss of capability of using the technological devices tested in the project.

[Additional exclusion criteria could be considered in each pilot according to the UNCAP configuration and local setting].

7.1.13. Randomization procedures

Randomization will be performed through specific software on a centre-by-centre basis.



7.1.14. Treatments procedure

After a baseline examination, included subjects signing an informed consent will be recruited; health-related information and case history data will be collected.

UNCAP features [tick the UNCAP features implemented]:

- ☐ UC1 – Access electronic health record
- ☐ UC2.1- Serious game for cognitive rehabilitation
- ☐ UC2.2 – measuring physical activity (tracking)
- ☐ UC2.3 – elderly localization and tracking
- ☐ UC2.4 – Blood glucose measurement
- ☐ UC2.5- blood pressure measurement
- ☐ UC2.6 – heart rate measurement
- ☐ UC2.7 – blood oxygen saturation measurement
- ☐ UC2.8 – Respiratory monitoring
- ☐ UC2.9 – Hydration monitoring
- ☐ UC2.10 – weight monitoring
- ☐ UC2.11 – stress measurement
- ☐ UC2.12 – Alertness monitoring
- ☐ UC2.13 – Multidimensional assessment (ATL@NTE)
- ☐ UC3 – Device localization
- ☐ UC4 – Fall detection
- ☐ UC5 – Fall prevention
- ☐ UC6 - Red button activation
- ☐ UC7 – Elderly person's motion analysis
- ☐ UC8.1 – Set alert notification
- ☐ UC8.2 – Set reminder notification
- ☐ UC9 – Interaction with the environment
- ☐ UC10.1 – remote communication for consulting
- ☐ UC10.2 – remote communication for social
- ☐ UC11 – Access entertainment functions
- ☐ UC12 – production of reference dataset

[Insert description of the settings in which standard care and UNCAP are implemented].

[Describe how each of the selected features will be implemented]

7.1.15. Study procedure

[Insert description of subjects' training and evaluation protocol in the specific pilot setting]

Study timeline:

TIMELINE	Test group	Control Group
<i>T0 (Enrolment time)</i>		
• Subject enrolment	x	
○ Check of Inclusion/exclusion criteria	x	
○ First evaluation with Atl@nte	x	
○ Informed consent	x	
• Filling the enrolment DCF	x	
• Randomization and group assignment.	x	
<i>T1: (UNCAP first time subject exposure for test group)</i>		
• <i>[Installation of UNCAP at home]</i>	x	
• Subject's training	x	
<i>T2: (Starting of the evaluation period)</i>		
• Use of the UNCAP	x	
• Assessment with Atl@nte <i>[every 3 months]</i>	x	x
• Filling the starting DCF	x	x
<i>T3: (End of the evaluation period)</i>		
• Assessment with Atl@nte	x	x
• Filling of the final DCF	x	x

7.1.16. Criteria for discontinuing subjects

A subject may voluntarily elect to discontinue his/her participation in the study at any time.

If, at any time, the investigator determines it is not in the best interest of the subject to continue in the trial, the subject will be excluded from the study.

If the subject fails to follow the procedures of the study, the investigator may discontinue the subject's participation in the study and will document it in the study file.

The reason for removal of a subject from the study should be documented.

7.1.17. Data handling

To guarantee subject's privacy, a table with ID codes vs subject sensitive data will be generated and stored by the responsible of the pilot site (Annex II). Electronic data collection form will be used and anonymized data will be stored and managed by project partners SocialIT (Italy) (data strictly related with Atl@nte) and Chino.IO (Italy) (data collected through the UNCAP platform). Anonymized data will be used for subsequent statistical analysis by the project partner ATOS (Spain). No data will be entered that may disclose the identity of a participant.

7.1.18. Outcome variables

Note:

This set of indicators is indicative and it needs to be validated by the Medical Committee by the end of November

Clinical status and subject's autonomy:

- Personal Health Profile (PHP) key from ATL@NTE, composed by the following evaluation items (ANNEX VIII)
 - Cognitive Performance Scale (CPS);
 - Depression Rating Scale (DRS);
 - Activities of Daily Living (ADL) Self-performance Hierarchy Scale;
 - Instrumental Activities of Daily Living (IADL) Difficulty Scale;
 - Pain Scale;
 - Physical Functioning: Transfer, Locomotion in home, and Eating;
 - Changes in Health, End-stage disease and Signs and Symptoms (CHESS);
 - Potential Problems;
 - Methods for Assigning Priority Levels (MAPLe);
 - Resource Utilization Groups III/HC (RUG) for Home Care

Safety:

- Number of adverse events;
- Number of Serious Adverse Events (SAE);
- Adverse device effect, an adverse event related to the use of the investigational medical device;
- Serious Adverse Device Effect (SADE), that is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Context analysis and impact:

- Number of medical examinations by general practitioner;
- Number of medical examinations by other physicians;
- Number of referrals to the emergency department;
- Number of hours per month spent by nurses taking care of subject;
- Number of hours per month spent by physicians taking care of subject;
- Number of hours per month spent by informal caregiver taking care of subject;
- Number of days off work for family members;
- Number of technical interventions for device malfunction.

7.1.19. Statistical analysis

Descriptive analysis will be performed for each single pilot. Test and control groups will be compared according to outcomes variables using statistical methods (average, typical deviation, etc.). A meta-analysis of the results obtained from the various pilot studies will be performed. Possible correlations among variables will be considered and the foreseen enhancement will be evaluated also in terms of confidence intervals.

7.1.20. Subject's economic implications

Subject's participation to the study is voluntary. Whatever treatment will be associated with the subject enrolled in the study (treatment group or control group), any additional costs, specifically related to the study procedures (UNCAP installation and training, Atl@nte assessment) will not be charged to the subject.

7.1.21. Management and notification of serious adverse events

The clinical investigator is in charge of revealing any adverse event occurring to the subjects involved in the study and potentially related to the experimental treatment. Adverse events will be recorded in the specific field on the data collection form.

Any adverse event that have:

- Led to a death;
- Led to serious deterioration in health that either:
 - resulted in a life-threatening illness or injury, or
 - resulted in a permanent impairment of a body structure or a body function, or
 - required in-patient hospitalization or prolongation of existing hospitalization, or
 - resulted in medical or surgical intervention to prevent life threatening illness or
 - injury or permanent impairment to a body structure or a body function.

In case of Serious Adverse Event - SAE, a notification should be provided by the clinical investigation sponsor to the local Ethical Committee and to the National Competent Authority (NCA) according to the procedure required for medical device



surveillance. A template for the SAE reporting form is available in the Appendix of MEDDEV 2.7.3 “Clinical investigations: serious adverse event reporting” [1].

Should the occurrence of the adverse events be considered clinically non acceptable, the study is stopped and the experimental protocol subjected to revision.

7.1.22. Funding

This study will be funded under the H2020 project UNCAP, Grant Agreement Number 643555.

7.1.23. Result handling and diffusion

The investigators shall own all rights in and to the publication of results compiled under their direction.

Given the nature of the project, which is a Pilot on Open Research Data initiative, all data generated during the piloting phase and collected by the platform will be made available in an anonymous form. Data and relative metadata will be accessible from the official website of the project (www.uncap.eu) upon the registration of an account, managed by the project coordinator, to ensure traceability of the shared information. Particular attention is paid to assure the highest possible protection of personal/sensitive information by anonymizing (and aggregating where needed) data before sharing them.

7.2. Data Collection Forms

For clinical effectiveness, the following ATL@NTE InterRAI assessment forms will be used:

- HC-Home Care;
- CHA- Community Health;
- LTCF-Long Term Care Facilities.

A data collection form for caregivers (a proposed one in Annex III-*to be revised with the validated indicators*) will be used to collect impact and organization related data. The form should be filled at the end of the experimentation period. Since this duty requires keeping track of events that could occur all over the experimentation period, a diary is also proposed (ANNEX IV). An adverse event reporting form is also proposed in Annex V.

8. Informed consent

8.1. Subject information and informed consent

The structure must inform the subject about her/his rights, the nature and motivation of the study and the personal data treatment. Before enrolment, the structure must collect and store signed informed consent from the subject under the responsibility of principal investigator.

A template for subject information and informed consent is reported as ANNEX VI.

9. Other documents

9.1.1. Insurance for the principal investigator

All the involved states require an insurance or indemnity to cover the liability of the investigator and sponsor.

9.1.2. Declaration of additional cost

A declaration of additional cost for the healthcare institution may be included if required by the local ethical committee.

9.1.3. Notification to the national health authority

In case of investigation with medical devices without CE marking, the sponsor should notify the national health authority at least 60 days before the start of the study (a fee is usually required).

The notification should include:

- Clinical investigation identification and status;
- Details about the manufacturer/ sponsor;
- Characteristics of the medical device;
- Description of the clinical investigation;
- Copy of clinical investigation insurance policy covering the participating subjects;
- Subject information and consent form;
- Copy of the opinion of the Ethics Committee (or copy of the ethics committee interrogation for Class I and II non implantable medical devices);
- Declaration of conformity with essential requirements (must include a clinical evaluation).

A template for notification is reported in Annex I. The project coordinator will provide all the technical details (technical note, manuals, risk assessment, clinical evaluation of the device according to MEDDEV 2.7.1 Rev.3: "Clinical Evaluation: A Guide for Manufacturers and Notified Bodies") [2].

Instructions can be found in the following table:

D7.8 – Template for ethical approval and informed consent		
File: D.7.8 - Template for ethical approval and informed consent.docx		Page: 18 of 40

Italy	http://www.salute.gov.it/portale/ministro/p4_8_0.jsp?lingua=italiano&label=servizionline&idMat=DM&idAmb=SC&idSrv=ICPRE&flag=P
Germany	http://www.dimdi.de/static/en/mpg/ismg/kplp/index.htm
Romania	http://www.anm.ro/anmdm/dm.html
Slovenia	http://www.jazmp.si/en/medical_devices/clinical_investigations_of_medical_devices_and_studies_for_performance_evaluation_of_in_vitro_diagnostic_medical_devices/
Greece	http://www.eof.gr/web/guest;jsessionid=6543ad4f3df879c3491c70c07edf
Macedonia	http://www.reglek.com.mk/

Additional details are available within the full guidelines of the European Commission on how to carry on clinical evaluation [2], conducting clinical investigations [3] and serious adverse event reporting [1].

9.1.4. Notification to the Data Protection Authority

Since the UNCAP pilot will deal with data disclosing geographic location of individuals by means of an electronic communications network, a further notification to the Data Protection Authority may be required.

9.1.5. Investigator's Brochure (IB)

The investigator's brochure should include:

- General information about the study:
 - Reference number;
 - Confidentiality;
 - Sponsor;
 - Scientific responsible;
- Rationale;
- Study protocol;
- Data Collection Forms;
- Description of the medical device and its components;
- Manuals.
- Risk analysis and risk management procedure to avoid undue risks;
- List of applied standards and normative.

9.1.6. CV of principal investigator

The curriculum vitae of the principal investigator must be included



9.1.7. Labelling

With regard to labelling the UNCAP devices to be used for the pilots shall not carry the CE-mark but be labelled with the inscription “Exclusively for clinical investigation”. The labelling must comply with applicable essential requirement of the medical device directives 90/385/EEC [4] (ANNEX 1, section 14) and 93/42/EEC (ANNEX 1, section 13) as implemented in national laws.



10. Conclusions

The template included in this reports represents a common framework to which each partner should adhere in order to conduct the clinical investigation conforming to current EU guidelines. Adjustments and modifications to the protocol are be possible if they will reflect the specific local settings and requirements.



ANNEX I – Notification form

Notification Form²

Clinical Investigation of Medical Devices

This notification form is intended for clinical investigation of non-CE marked medical devices, or medical devices CE-marked for a different purpose than intended in the clinical investigation.

Please send the completed form to the National Competent Authority (NCA) for medical devices.

The content of fields with blue label will be uploaded into the Eudamed (European Database on Medical Devices) database for Clinical Investigation (CI) of medical devices.

The notification should be presented by the sponsor. The project coordinator will help them fill in the form.

1. Clinical investigation identification and status	
Submission type select submission type	NCA registration number (CA Reference), if applicable fill in text
Submission date select date	EUDAMED identification number, if applicable (CIV-YY-MM-XXXXXX) fill in Eudamed identification number (CIV-)
Has an application for clinical investigation of a medicinal product linked to this notification been submitted to the NCA or will it be submitted? select Yes / No	EudraCT number, if applicable fill in text
Title of the clinical investigation fill in text	Clinical Investigation Plan (CIP) code fill in text Version and date of the CIP fill in text

² Each country may have its dedicated form in original language. However, the presented form contains all the information required at European level, so, once filled, it can be used to prepare national form.



2. Manufacturer		
Name fill in text		Contact for this Clinical investigation, name fill in text
Street/road fill in text	Number/house/floor fill in text	Phone fill in text
Postal code fill in text	City fill in text	Fax fill in text
State/region fill in text	Country select country	E- mail fill in text

3. Authorised Representative within the EEA, if applicable		
Name fill in text		Contact for this Clinical investigation, name fill in text
Street/road fill in text	Number/house/floor fill in text	Phone fill in text
Postal code fill in text	City fill in text	Fax fill in text
State/region fill in text	Country select country	E- mail fill in text

4. Sponsor, according to the EN ISO 14155 [6] definition, if other than manufacturer or authorised representative, if applicable:		
Name fill in text		Contact for this Clinical investigation, name fill in text
Street/road fill in text	Number/house/floor fill in text	Phone fill in text
Postal code fill in text	City fill in text	Fax fill in text
State/region fill in text	Country select country	E- mail fill in text

5. Medical device to be investigated	
Name of the medical device fill in text	Model or version fill in text
Generic name of the medical device (if name not specified above)	GMDN (Global Medical Device Nomenclature) code



fill in text	fill in text
Name used elsewhere to market same medical device fill in text	Other internationally recognized nomenclature fill in text
Is the medical device CE-marked for other use than intended for this CI? select Yes / No	Class of device select class of device
Intended use of the medical device in the CI fill in text	
Description of the medical device fill in text	
6. Additional information of the medical device to be investigated	
Is a medicinal product integrated with the medical device or shall a medicinal product act together with it?	select Yes / No
Does the medical device incorporate, as an integral part, a human blood derivate?	select Yes / No
Have tissues of animal origin been used in the manufacturing process?	select Yes / No

7. Comparator medical device(s) (if applicable)	
Manufacturer fill in text	GMDN code fill in text
Name of the medical device, model or version fill in text	Other nomenclature fill in text
Product class	select class of device
Is the medical device CE-marked for the intended use in this CI?	select Yes / No
Is a medicinal product integrated with the medical device or shall a medicinal product act together with it?	select Yes / No

8. Clinical investigation			
Primary objective fill in text			
Inclusion criteria fill in text		Exclusion criteria fill in text	
Planned total number of subjects involved fill in text	Planned number of subjects in the NCA state fill in text	Planned start date of CI select date	Planned completion date of CI select date



Planned states within EEA, Switzerland and Turkey for the CI

- | | | |
|---|--|---|
| <input type="checkbox"/> Austria | <input type="checkbox"/> Greece | <input type="checkbox"/> Norway |
| <input type="checkbox"/> Belgium | <input type="checkbox"/> Hungary | <input type="checkbox"/> Poland |
| <input type="checkbox"/> Bulgaria | <input type="checkbox"/> Iceland | <input type="checkbox"/> Portugal |
| <input type="checkbox"/> Croatia | <input type="checkbox"/> Ireland | <input type="checkbox"/> Romania |
| <input type="checkbox"/> Cyprus | <input type="checkbox"/> Italy | <input type="checkbox"/> Slovakia |
| <input type="checkbox"/> Czech Republic | <input type="checkbox"/> Latvia | <input type="checkbox"/> Slovenia |
| <input type="checkbox"/> Denmark | <input type="checkbox"/> Liechtenstein | <input type="checkbox"/> Spain |
| <input type="checkbox"/> Estonia | <input type="checkbox"/> Lithuania | <input type="checkbox"/> Sweden |
| <input type="checkbox"/> Finland | <input type="checkbox"/> Luxembourg | <input type="checkbox"/> Switzerland |
| <input type="checkbox"/> France | <input type="checkbox"/> Malta | <input type="checkbox"/> Turkey |
| <input type="checkbox"/> Germany | <input type="checkbox"/> Netherlands | <input type="checkbox"/> United Kingdom |

9. Clinical investigation – Design and additional information

Area of investigation

- ☐ Cardiology ☐ Surgery ☐ Orthopaedics ☐ Oncology ☐ Radiology ☐ Other

Secondary objective(s)

fill in text

Summary of clinical investigation plan

fill in text

Controlled study?

select Yes / No

If controlled

☐ Parallel groups

☐ Cross over

☐ Other

Randomization?

select Yes / No

Masking

☐ Open

☐ Single blinded

☐ Double blinded

☐ Blinded evaluation

Gender

select Men/Women/Both

Subjects <18 yrs?

select Yes / No

If yes, which ages?

fill in text

Countries outside EEA, Switzerland and Turkey participating in the CI?

select Yes / No

If yes, which?

fill in text

10. Mandatory attachments

Clinical Investigation Plan, Clinical Investigation Plan (CIP)

select Yes / No

Investigator's Brochure (IB)

select Yes / No

Copy of clinical investigation insurance policy covering the participating subjects

select Yes / No

Subject information and consent form (in national language)

select Yes / No

Copy of the opinion of the Ethics Committee if available

select Yes / No

List of National investigations site(s), Clinical Investigator (s)

select Yes / No

D7.8 – Template for ethical approval and informed consent

File: D.7.8 - Template for ethical approval and informed consent.docx

Page: 25 of 40



Qualifications of the principal investigator and one investigator per site	select Yes / No
Declaration of conformity with Essential Requirements	select Yes / No
11. Attachments, if not included in the IB, as applicable	
Results of risk analysis	select Yes / No
List of applied standards: Standards applied in full and description of deviations from applicable harmonised European standards.	select Yes / No
Documentation on tissues of animal origin in the investigational device	select Yes / No
Documentation on human blood derivate in the investigational device	select Yes / No
Documentation on medicinal substances in the investigational device	select Yes / No
Documentation of products/drugs/substances which the device under investigation will be used together / co-act / be compared with	select Yes / No
Intended device labelling	select Yes / No
Instructions for use to subjects (in national language) or professional users	select Yes / No
Case Report Form (CRF)	select Yes / No
Evaluation forms to be filled in by subjects or staff (in national language)	select Yes / No
Copy of the application to the Ethics Committee	select Yes / No

12. Signature	
Sponsor / Manufacturer / Authorized representative (if applicable)	<p>I hereby certify that information provided in this notification is correct and I will see to that the investigation is carried out in accordance with the Declaration of Helsinki, applicable medical device directives, national regulations, EN ISO 14155 and the attached investigation plan.</p> <p>I keep available upon request documentation mentioned in annex 8 of directive 93/42/EEC and/or annex 6 of directive 90/385/EEC.</p> <p>Date and signature</p> <p>fill in text</p> <p>.....</p> <p>Name fill in text</p>



ANNEX II - Matching sheet

Matching sheet (proposed)

(to be compiled and stored by the pilot site's responsible)

Subject Identificative Number (ID):

Subject name: _____

Subject surname: _____

Birth date: ____/____/____

Sex: ☐ M ☐ F

Cognitive impairments: _____

CPS scale: _____

Co-morbidity: _____

Randomization result:

☐ Test ☐ Control



ANNEX III – Data collection form

Data collection form for caregivers (proposed)

(to be filled at the end of T3)

Subject's ID: _____

Starting of T2: __/__/__

End of the study T3: __/__/__

Please score the following:

Indicators	Number
Number of medical examination by general practitioner	
Number of medical examination by other physicians	
Number of referrals to the emergency department	
Number of hours per month spent by nurses taking care of subject	
Number of hours per month spent by physicians taking care of subject	
Number of hours per month spent by informal caregiver taking care of subject	
Number of days off work for family members	
Number of interventions for device malfunction	

Caregiver's signature and date: _____



ANNEX IV – Caregiver Diary

Caregiver Diary

(to be filled by the caregiver at each occurrence starting from T2)

Caregiver: _____

Subject ID: _____

T2: __/__/__

Date of occurrence	Medical examination by GP	Medical examination by other physician	Referrals to emergency department	Hour/month spent by the caregiver	Days off work for family members	Interventions for device malfunction	Caregiver signature
__/__/__	[Note]						



ANNEX V – Adverse event reporting form

Adverse event reporting form

Subject ID: _____

Study Centre: _____

Date of First Use on investigational device: _____

Date of Event Onset: _____

Involved Organ/System: _____

Description of event: _____

Action/treatment/patient outcome: _____

Assessment of relationship to procedure:

☐ Yes ☐ No ☐ Possibly

Assessment of relationship to investigational device:

☐ Yes ☐ No ☐ Possibly

Treatment arm:

☐ test group ☐ Control group

Event Status:

☐ Resolved ☐ Resolved with sequelae ☐ Ongoing ☐ Death

Date of event resolution (if resolved): _____



ANNEX VI – Subject's information

Subject's information

The safety of our *[guests]* is our main priority!

That is the main reason for which our nursing home has decided to participate in an international project called UNCAP (Ubiquitous iNteroperable Care for Ageing People).

The purpose of this project is to study new technologies and new ways of working that allow us to be able to offer an always better service.

When you feel fragile, you need constant care, whether you are in a nursing facility or at home.

[Knowing that you can count on someone even when you are alone is a goal that all patients would achieve. Many patients are forced to change health facilities several times, while they could be treated at home with modern technologies.]

Being able to move during the stay in the facility or to know that even at home there is the possibility to be constantly followed by the structure and by doctors allows patients to re-achieve more quickly their skills and independence and live diseases in a more serene way.

UNCAP uses modern technologies to help you maintain your dignity, autonomy, and a qualitative good level of life for a longer period.

In particular, the project to which we ask you to participate has these basic goals:

- a) To study and develop IT tools, technology, video surveillance, remote monitoring of vital signs that can allow a greater freedom of movement inside and outside the *structure/home*, *[thus guaranteeing the possibility of intervention in emergency situations]*.
- b) To allow the staff to be able to control from a distance in order to intervene in a more accurate way. The projects that we intend to implement are based on location through cameras and other computer equipment.

All this will take place with full transparency and with the obligation to respect it in all circumstances by the organizations participating in the project.

Your Participation is completely voluntary.

Before deciding whether to participate, you must read the following information and seek clarification from the physician who will follow you.

Procedures

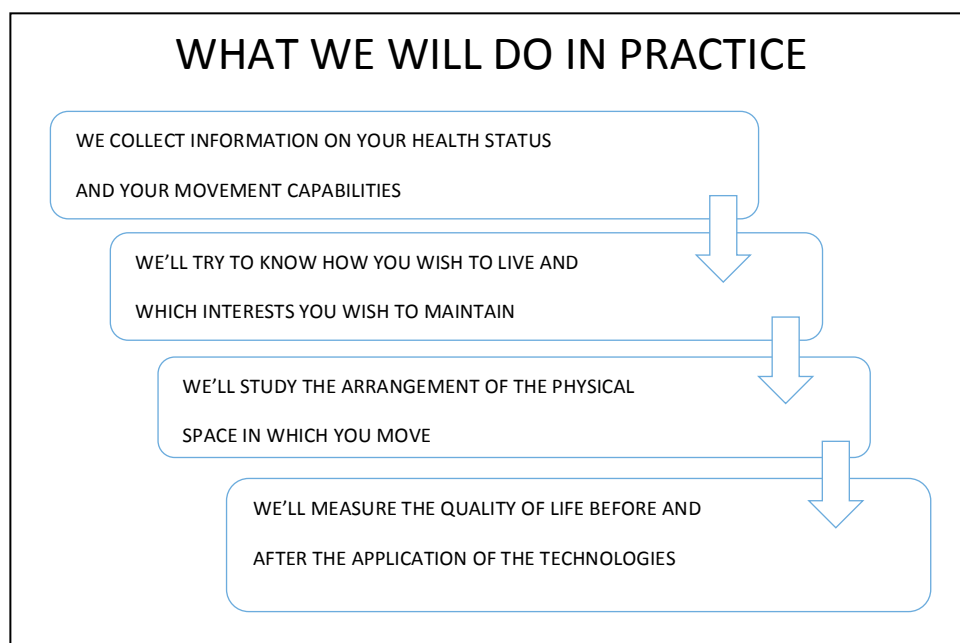
In order to do so, we intend to study and develop technologies that allow us to assist in the best way, but that leave you free to live in absolute confidentiality when needed.

[Please describe in a simple way the planned intervention and the motivations behind]

[E.g. Some of these technologies allow us to locate patients in every moment of their life within the structure and / or at their doorstep]. [This allows us (nurse or caregiver) to be able to identify and see if and when they are in danger or distress. Or this allows us to check your physical activities and compliance]

Some of these tools are already available, such as cameras, sensors and telemedicine tools and must be implemented according to the rules that this draft study will show us. Others, however, have to be invented, designed and built specifically so as to achieve this goal.

We ask you to be part of this change. For your health and that of the people in need around the world.



To carry on this study, the information that we need to collect is the following:

- Basic personal data (name, birth data, ethnicity, address, phone number, names of people in the family that the patient wants to keep close).
- Where do the patients live, that is if their house or structure have architectural barriers and which are the dangers that we have to keep in mind for their safety.
- The medical history and the severity of their condition.
- The degree of autonomy to perform daily living activities such as bathing, cooking, walking with or without help.
- Hospitalizations.
- Number of visits to the GP.
- Number of visits to the specialists;
- *[The social history and the places the patients love to attend;]*



- People who are caring and that can intervene in case of need, e.g. the neighbours, caregivers, etc.
- The history and the circumstances of his/her previous falls.
- *[Clinical parameters such as blood pressure....or level of stress]*
- *[add other relevant points for your specific study design]*

The technology applied to these devices activates alarm signals in particular conditions to draw the attention of doctors and nurses.

- c) To study tools that allow medical staff and nurses to come to the rescue when the patient is at home and/or outside the structure.
- d) To develop tools that can be adapted to patient's house. The practical application will be made only with his/her specific consent.
- e) To publish the study data, in anonymous and aggregate form, and to make them available to designers and health facilities around the world.

Risks and discomforts

The study does not need to add any type of active substance, drug and / or supplement to your care.

It requires no invasive clinical procedure than the one necessary for your treatment path.

The study does not imply more clinical risks than those already in your usual course of treatment.

You will be free in your movements but, only in the case of implementation of all or part of the systems, the structure will be able to identify the place, your vital parameters and your geographical position.

You are free to not participate in the study or to leave the study at any time without any penalty. In this case, you will continue to receive all standard cares planned for your condition and the doctors and nurses will continue to follow you with due care welfare.

Data processing

In order to proceed to the study we need to know exactly the health care needs of our guests, so it is necessary that you authorize us to process your personal data and those relating to your medical condition for these specific study activities.

[Part of the information concerning them and useful to the compilation of your medical record is already in possession of the structure: for example name, address, medical history, diseases and medicines that you take.]

Other information will be requested through an interview that will concern you and the people who are close to you. You will be free to answer or not the questions. If you do not answer, we will not be able to collect quality data and, consequently, the study may not be accurate. In this case, at the discretion of the structure, you will be excluded from subsequent testing phases.

The data used in the project will be collected in a particular medical record, since we have to activate a route allowing you to know if, and how, your conditions have been



improved, and that will allow us to extract, in an anonymous and statistical information useful for the evaluation of the technologies described above.

Who will use data

- A. **The [please write the name of your institution]** with your collaboration and that of the doctors that treats you, will be responsible for the processing of your personal data.

[Only the staff of the nursing home] will have access to medical records. The data useful to the project will be provided to the Providers of hosting services (CHINO.IO and SocialIT). The data aggregated and anonymous will then be combined with other data from other healthcare facilities so that they can be compared, by combining experiences and the best care activities.

[Be careful, if video or images are used to localize or track people the procedures for using and storing them must be described in details. E.g. Storing of images and electronic tracks will remain in the structure. (Access can only be granted to personnel in charge and only in order to protect your health, safety and to allow an immediate intervention.) The images and electronic tracks will be preserved for 48 hours and then destroyed.]

[For emergency case (fall, etc.) the responsibility for the actions to take should be clearly identified and stated. Is fall detection in real time? Who is going to be notified in case of fall and how? Who is going to intervene in case of fall detection at home?]

The controller designated by the nursing home is

- B. **Project partners** will have access only to the aggregated data. Should it be necessary to access your data, it will do so only through your doctor, so that your personal and health-related data will always be reserved.

The presence of instruments of control within the facility will ensure in any case the confidentiality of all clinical and biological activities.

- C. **CHINO.IO** is a company specialized in the secure storage for health data according to EU privacy laws. It will be responsible for the security and privacy of data collected through UNCAP based on a commercial contract to provide such a service.

- D. **SOCIAL-IT** is a company specialized in the development of the software (Atl@nte) that will be used to evaluate UNCAP. Its role is of system administration and responsible for the security and privacy of data collected through Atl@nte.

In particular, it will made available to the nursing home a medical record called "Atl@nte" whose purpose is to re-order, compare, and extract anonymous data and information collected through your participation.

From the medical records, statistical models and comparison of care pathways will be developed.

Both Chino.IO and Social.IT may use companies specialized in data retention that will operate with duty of confidentiality and the prohibition of direct access data.

Data will be stored on computer platforms able to ensure maximum confidentiality and security of data.



The storage location of the data is in Italy and / or in another European country that provides a similar or higher degree of security protection.

No transfer of data will be made outside the European community.

E. **HEALTH PROFESSIONALS OF THE STRUCTURE.** Only doctors and the nursing staff will have direct access to your medical records. The personal and health data will be extracted in an anonymous and aggregate way and can be further aggregated with those from nursing homes that participate in the European industrial and healthcare research project.

F. In the project, other persons responsible will intervene, such as technicians, doctors, statisticians, engineers specifically appointed responsible of the treatment by one of the parties and kept to the absolute requirement of confidentiality and secrecy.

Your rights

The keeping of medical records is a requirement of the structure and that does not change if you adhere to the project or not.

You are free to withdraw at any time without prejudice for your future care or the right to assistance.

You will continue to use the services already ensured and will keep the relationship with your doctor.

In providing the care/assistance service, the *[name of institution]* will operate with competence and professional diligence and respecting confidentiality and ensuring protection of sensitive data and confidential information concerning the patient or his/her family.

The Clinic is committed to providing accurate and timely information on the mode of operation of the organization and on the professionals to whom to turn for your different needs.

Clinical data will be stored by the nursing home for a time commensurate with the objective to reach statistical and scientific results and for two years after the closure of the project.

Aggregated data will be stored by the provider for as long as necessary in view of the future enlargement of the trial, but no later than five years from the end of the project.

Each person participating in the trial within his/her competence is aware of the responsibilities required by the standards of good clinical practice in compliance with the European Directive 95/46/EE of the European Parliament and of the Council of 24 October 1995 [7] and by national laws for the processing of personal data.

Your personal and sensitive data will be processed through papers and electronic formats by the partners involved in the project, and will be accessible to the staff in order to dispense you care services.

All stakeholders and staff are obliged to respect the confidentiality of information learned in the course of the activities that will be made.



[Your medical record is also used to follow your healthcare path. The data included therein cannot be deleted but can be blacked out in one or more part if you deem it necessary.]

You may instead withdraw the authorization to the processing of data for the purposes of the research project at any time.

The technical systems used will conform to the indications of the best technological knowledge and to the laws for their conservation and protection.

The data processed using electronic tools will be disclosed only in an anonymous form, such as through scientific papers, statistics and scientific meetings.

All technological systems will be kept within the European Community with the application of the best conservation techniques given through instruments guaranteed under every technical, legislative and security point of view.

All those who participate in the project are required to comply with the confidentiality and professional secrecy.

You, as subject of the treatment, have the following rights:

1. You have the right to obtain confirmation as to whether or not personal data concerning you exist, regardless of their being already recorded, and communication of such data in intelligible form.
2. You have the right to be informed:
 - a) of the source of the personal data;
 - b) of the purposes and methods of the processing;
 - c) of the logic applied to the processing, if the latter is carried out with the help of electronic means;
 - d) of the identification data concerning data controller, data processors and the representative designated according to the instructions of the project and in compliance with the regulations in the State of the nursing home;
 - e) of the entities or categories of entity to whom or which the personal data may be communicated and who or which may get to know said data in their capacity as designated representative(s) in the State's territory, data processor(s) or person(s) in charge of the processing.
3. You have the right to obtain:
 - a) updating, rectification or, where interested therein, integration of the data;
 - b) erasure, anonymization or blocking of data that have been processed unlawfully, including data whose retention is unnecessary for the purposes for which they have been collected or subsequently processed;
 - c) certification to the effect that the operations as per letters a) and b) have been notified, as also related to their contents, to the entities to whom or which the data were communicated or disseminated, unless this requirement proves impossible or involves a manifestly disproportionate effort compared with the right that is to be protected.
4. You have the right to object, in whole or in part,



- a) on legitimate grounds, to the processing of personal data concerning him/her, even though they are relevant to the purpose of the collection;
- b) to the processing of personal data concerning him/her, where it is carried out for the purpose of sending advertising materials or direct selling or else for the performance of market or commercial communication surveys.

[name of the institution] has designated as responsible of the treatment, to whom you may direct any requests for exercising the rights referred to in the previous paragraph, as responsible for the replay.

Social-it is responsible of treatment for the purposes of conservation and extraction of the data collected with Atl@nte and management of the platform on which the data will reside. The role is technical and for this purpose the appointed system administrator of system is Mr.

Chino.IO is responsible of treatment for the purposes of conservation and extraction of the data collected with UNCAP and management of the platform on which the data will reside. The role is technical and for this purpose the appointed system administrator of system is Mr.

To exercise your rights or for any other information you can address to
[please, add the name of the of data treatment in your organisation].



ANNEX VII – Informed consent

SUBJECT'S DECLARATION OF INFORMED CONSENT

I the undersigned

Last Name	
Name	
Date Of Birth	
Fiscal Code or National Insurance Number	
Other data	
Telephone Number / Email	
Legal representative in the case of patients who are unable to give consent	

DECLARE

1. I understand to participate in an experimental management of chronic patients as illustrated in the agreement signed with the nursing home;
2. I understand that I can withdraw at any time from the project without incurring in any obstacle and without jeopardizing the continuity of my care;
3. I have been informed by the nursing home on the rights to privacy of personal data within the meaning of the European directive and that I understand that these data will be used exclusively for the management of activities related to the project.



I have read (or someone has read to me) the information provided in the previous pages. I was given the opportunity to ask questions and received satisfactory answers. I was also given a copy of this form.

In addition,

___ I CONSENT TO PARTICIPATE IN THE PROJECT AND AGREE TO THE PROCESSING OF MY DATA REFERRED TO THE EXTENT OF WHAT WRITTEN ABOVE

Name of the subject

Name of subject's legal representative (if appropriate)

Signature of the person or legal representative

Date

SIGNATURE OF THE DOCTOR THAT PROVIDES THE INFORMATION

I have explained the study to / to Mr / Ms
and / or to his/her legal representative and I answered all his/her questions. I think he/she understood the information provided and contained in this document and has given his/her voluntarily consent to the participation and to the processing of personal data within the limits indicated above.

Name of the investigator

Signature of the Investigator

Date

(must be the same as the signature
of the subject)

ANNEX VIII – Atl@nte scales definition

Personal Health Profile Key

Cognitive Performance Scale (CPS) Scores range from 0 to 6. Scores are based on skills for daily decision-making, making self understood, and short-term memory recall. "Eating impairment" differentiates a score of 5 or 6. Higher scores indicate a greater degree of cognitive impairment.			Physical Functioning: Transfer, Locomotion in home, and Eating	
Score	Description	Equivalent Average MMSE	Independent	No help, setup, or oversight - OR - help, setup, oversight provided only 1 or 2 times
0	Intact	25	Setup Help	Article or device provided within reach 3 or more times
1	Borderline intact	22	Supervision	Oversight, encouragement, or cueing provided 3 or more times during last 3 days - OR - supervision (1 or more times) plus physical assistance provided only 1 or 2 times
2	Mild impairment	19	Limited Assistance	Client highly involved in activity; received physical help in guided maneuvering of limbs or other non-weightbearing assistance 3 or more times - OR - combination of non-weightbearing help with more help provided only 1 or 2 times during period
3	Moderate impairment	15	Extensive Assistance	Client performed part of activity on own (50% or more of subtasks) but help of following type(s) provided 3 or more times: weight-bearing support - OR - full performance by another during part of period
4	Moderate/severe impairment	7	Maximal Assistance	Client involved and completed less than 50% of subtasks on own (includes 2+ person assist), received weightbearing help or full performance of certain subtasks 3 or more times
5	Severe impairment	5	Total Dependence	Full performance of activity by another
6	Very severe impairment	1	Did Not Occur	(regardless of ability)
Depression Rating Scale (DRS) Scores range from 0 to 14. The DRS is based on 7 MDS-HC items: negative statements, persistent anger, expressions of unrealistic fears, repetitive health complaints, repetitive anxious complaints, sad or worried facial expression, and tearfulness. A score of 3 or greater suggests possible depression.			Changes in Health, End-stage disease and Signs and Symptoms (CHESS) Scores range from 0 to 5. CHESS measures medical complexity and health instability, based on: vomiting, dehydration, leaving food uneaten, weight loss, shortness of breath, edema, end-stage disease, and decline in cognition and ADL. Higher scores indicate higher levels of medical complexity.	
ADL Self-performance Hierarchy Scale Scores range from 0 to 6. The ADL Hierarchy measures activities of daily living performance according to early, middle, and late stages of loss using 4 ADLs: personal hygiene, toilet use, locomotion, & eating.			Potential Problems Psychotropic drugs: Identifies persons taking psychotropic drugs and who need a medical review of their medication regimen, or who might benefit from more or different medical monitoring of psychotropic drug effects. Potential problem based on: use of psychotropic drug plus one or more of: delirium, cognitive or communication decline, active or worsening mood and behaviour, trouble walking, incontinence, Parkinsonism, delusions, hallucinations, falls, unsteady gait. Alcohol dependence: Identifies alcohol abuse or dependence. Potential problem based on: one or both of the alcohol-related items. Improvement in ADLs: Identifies potential for either greater independence in self-care or prolonged periods in which the risk of decline is lessened. Potential problem based on: ADL deficit is present, the client can understand others, and either a decline has occurred or a belief is present that improvement is possible. Falls: Identifies those for whom falls have occurred recently and if there is a risk of falling. Potential problem based on: history of falls, dementia, Parkinsonism, unsteady gait, does not limit going outdoors, change in mental function. Pressure Ulcer: Identifies those at risk for developing skin breakdown or who may require treatment for pressure ulcers that are present. Potential problem based on: presence or history of pressure ulcer; fecal incontinence; assistance with bed mobility.	
Score	Description		Methods for Assigning Priority Levels (MAPLe) Scores range from low to very high. MAPLe is calculated from MDS-HC items known to be predictive of facility admission, caregiver stress, or a feeling that the client would be better off elsewhere.	
0	Independent – all 4 ADLs either independent or setup help only		Low	Mild
1	Supervision required – 1 or more ADLs require supervision		Moderate	High
2	Limited impairment – 1 or more ADLs require limited assistance		Very High	
3	Extensive assistance required (I) – no more than limited assistance in eating or locomotion but toilet use or personal hygiene require extensive assistance or more			
4	Extensive assistance required (II) – no more than maximal assistance in eating or locomotion but toilet use or personal hygiene are totally dependent or did not occur			
5	Dependent – eating or locomotion is totally dependent or did not occur but at least one of 4 ADLs are less impaired			
6	Total dependence – 4 ADLs are either totally dependent or did not occur			
IADL Difficulty Scale Scores range from 0 to 6. The IADL Difficulty Scale measures Instrumental Activities of Daily Living capacity according to stages of loss using ordinary housework, meal preparation, and telephone use.			Resource Utilization Groups III/HC (RUG) for Home Care RUG III/HC places clients into one of these resource levels:	
Score	Description		1 - Special Rehabilitation (highest)	5 - Impaired Cognition
0	No difficulty in any of the 3 IADLs		2 - Extensive Services	6 - Behaviour Problems
1	Needs some help, is very slow, or fatigues in only 1 of 3 IADLs; no difficulty in other 2		3 - Special Care	7 - Reduced Physical Function (lowest)
2	Needs some help, is very slow, or fatigues in 2 of 3 IADLs; no difficulty in other 1		4 - Clinically Complex	
3	Needs some help, is very slow, or fatigues in all 3 of 3 IADLs			
4	Great difficulty, or no involvement is possible, in 1 of 3 IADLs			
5	Great difficulty, or no involvement is possible, in 2 of 3 IADLs			
6	Great difficulty, or no involvement is possible, in 3 of 3 IADLs			
Pain Scale Scores range from 0 to 3. Scores are based on two pain questions: pain frequency and pain intensity				
Score	Description			
0	No pain			
1	Mild pain – pain less than daily			
2	Moderate pain – daily pain that is mild or moderate			
3	Excruciating pain – daily pain that is severe or horrible			