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inCASA

Integrated Network for Completely Assisted Senior citizen's Autonomy

D6.4 Pilot Ethical Report

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Executive summary

At the current stage of the project, four inCASA pre-pilots have been deployed. One purpose of the pre-pilots is to record and resolve any unforeseen ethical issues before the full pilots are implemented. FHC does not have a pre-pilot stage. All pilots have obtained ethical approval from their relevant authorities as necessary.

This deliverable includes the pilots' completion of the Ethical Guideline Check List, and overall all pilots comply with the ethical requirements defined in the check list.

Four issues will require further discussion at the forthcoming Ethical Board meeting on 2 February 2012. These issues are:

- What assurances exist that the information collected is true and accurate?
    - The ATC pilot answers that data is being collected by the devices but does not specify how if and which assurances are in place to assure accuracy.
    - INSERM has answered "no" to this. In the INSERM pilot data is collected by patients and their accuracy is thus based on trust (that patients are being truthful).
    - The KGHNI pilot has answered that this is partially achieved as validation and review of the data collected will be carried out in cooperation between the doctors and patients every 1-2 weeks.

- Can the person whose data are collected easily rectify errors in personal data? What procedures are in place for doing so?
    - The KGHNI pilot has answered that this is partially achieved; there is no formal procedure in place but the patient will need to contact the doctor responsible.

- Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?
    - The KGHNI pilot has answered that this partially achieved; instructions on how to obtain a copy of the data and a description of the mechanism to correct any erroneous data is not included in the informed consent form. However, the latter is partially achieved as described in the issue above.

Finally, INSERM raises an additional ethical issue related to the technological solution, namely that parameters are not displayed in order to properly view changes over time. INSERM thus suggests that it may be necessary to extend the pre-pilot phase. This technological issue was raised at the technical meeting on 12 January 2012 and a solution has been proposed. The necessary improvements of the web portal are expected by mid/end February 2012.

1 Introduction

inCASA will create citizen-centric technologies and a services network to help and protect frail elderly people, prolonging the time they can live well in their own home. This goal will be achieved by integrating solutions/services for health/environment monitoring, which will collect and analyse data for profiling of user habits. Furthermore, to this end customized intelligent multilevel alerts/communication services will be implemented.

The inCASA project includes five pilot sites (in five different countries) which will each select 30-40 of their users to participate in the inCASA project. The users will be elderly people with chronic health conditions and/or frail people living alone who need some level of home assistance, care or support. Four of the five pilots will run a pre-pilot phase with a very limited number of end users (3-5). The purpose is to test and evaluate the services before rolling out the full pilot.

The inCASA project is committed to ensuring that the fundamental ethical principles are respected and that any ethical concern or issue is properly dealt with if and when it occurs. To achieve this end, the deliverable *D2.3 European country policies and ethical package* defined an ethical guideline check list which is intended as a tool for the pilots to assess whether they meet the project's defined ethical standards and requirements. This deliverable reports back from the pilots' completion of the Ethical Guideline Check List.

At the current stage of the project, four inCASA pre-pilots have been deployed. One purpose for the pre-pilots is to record and resolve any unforeseen ethical issues before the full pilots are implemented. The Spanish pilot Fundación Hospital Calahorra (FHC) will not have a pre-pilot stage.

The Agenzia Territoriale per la casa della Provincia di Torino (ATC) pre-pilot started in October 2011 and it focuses on providing telecare services to elderly living alone. It has three participants who have had sensors installed in their home. These sensors measure and transmit data regarding the person's movement, opening/closing of doors, temperature/ humidity and water leaks.

The Chorleywood Health Centre (CHC) pre-pilot started in April 2011 and its objectives include building the technical and clinical services that respond to remote patient monitoring (RPM), evaluating these services and understanding the impact on the patient's quality of life.

The Fundación Hospital Calahorra (FHC) pilot focuses on rehabilitation at home for elderly patients with chronic obstructive pulmonary disease (COPD) who live far from the hospital. A total of 30 patients will participate in the pilot. The pilot started in January 2012 when selected devices were installed in the homes of the first six patients.

The Institut National de la Sante et de la Recherche Medicale (INSERM) pilot focuses on providing continuous information on the conditions of elderly cancer patients at home. The INSERM pre-pilot started in November 2011. In January 2012, five patients had been recruited for the study. The inCASA platform was installed at their homes for the duration of the pre-pilot phase. The patients used it every day for body weight measurement and symptoms assessment according to the MD Anderson Symptom Inventory (MDASI).

The Konstantopouleio General Hospital of Nea Ionia (KGHNI) pilot focuses on monitoring elderly people suffering from Chronic Heart Failure. The pre-pilot phase started in October 2011 and was concluded in December 2011. Three (3) patients participated in the pre-pilot. The inCASA platform was installed at their homes for the duration of the pre-pilot phase. The patients used it every day for body weight measurement. In January 2012, additional patients have been recruited for the main pilot phase.

1.1 Purpose of this deliverable

This deliverable will present each pilot's ethical report. The purpose of this deliverable is threefold: 1) it documents whether each pilot complies with the ethical guidelines, 2) it allows reporting of any ethical concerns or actual ethical problems for the pilots, and 3) it contributes to the overall evaluation of the pilots.

1.2 Outline of this deliverable

Chapter Two presents the Ethical Guidelines Check List in full.

Chapter Three presents the Ethical Report of the Italian pilot – Agenzia Territoriale per la casa della Provincia di Torino (ATC).

Chapter Four presents the Ethical Report of the UK pilot – Chorleywood Health Centre (CHC).

Chapter Five presents the Ethical Report of the Spanish pilot – Fundación Hospital Calahorra (FHC).

Chapter Six presents the Ethical Report of the French pilot – Institut National de la Sante et de la Recherche Medicale (INSERM).

Chapter Seven presents the Ethical Report of the Greek pilot – Konstantopouleio General Hospital of Nea Ionia (KGHNI).

A conclusion based on the results of the pilot reports is given in Chapter Eight.

2 Ethical Guideline Check List

The following check list was first defined in the deliverable *D2.3 European country policies and ethical package*.

Pilot sites have been asked to use this check list and report back in the current deliverable. The following chapters will present each pilot site's feedback to this check list as well as any other ethical issues they have either encountered or foresee might arise.

Privacy and Data Protection

- Is information collected in ways of which the data subject is aware?
- Will the information be deleted when it is no longer needed for the purpose for which it was collected?
- Who will have access to or use of the data collected?
- Will the data be transferred to or shared with others without the person's awareness?
- Has the project taken steps to ensure that persons cannot be identified from the data to be collected?
- What assurances exist that the information collected is true and accurate?
- Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?
- Have measures been put in place to facilitate the person's access to his or her personal data?
- Can the person whose data are collected easily rectify errors in personal data? What procedures are in place for doing so?

Surveillance

- Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?
- How and for how long will images or data be retained?
- How will such images or data be used or erased?
- Who will authorise the surveillance practice, whether in private homes or assisted living residences?
- What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?

Autonomy

- Does the project curtail a person's right to liberty and security in any way?
- Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?
- Will the project use a technology to constrain a person or curtail their freedom of movement or association?

Dignity

- Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?
- Is such recognition explicitly articulated in statements to those involved in or affected by the project?
- Does the project compromise or violate human dignity? For example, does the project involve body scanners?
- Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?
- Does the project or service or application involve implants?

Informed Consent

- Has the project obtained the free and informed consent of those persons involved in or affected by the project?
- Has the person been informed of the nature, significance, implications and risks of the technology in question?
- Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?
- If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?
- Are people aware that personal data may be collected? Are they aware of who is collecting it and why?
- Has the person consented to collection of his personal data?
- Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?
- If the individual is not able to give informed consent (because, for example, the person suffers from dementia) for participation in a project or the use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?
- Has the person had an interview with a project representative in which he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?
- Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?
- Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?
- Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?
- Is consent given truly voluntarily? For example, does the person need to give consent in order to get a service to which there is no alternative?
- Does the person have to deliberately and consciously opt out in order *not* to receive the "service"?

3 Agenzia Territoriale per la casa della Provincia di Torino (ATC), Italy

The pre-pilot phase started in October 2011. Twenty persons had been recruited for the study: 3 for the pre-pilot and an additional 17 for the complete pilot. The inCASA platform has been installed in the participants' apartments. In the pre-pilot phase, the devices transmit data every day about the person's movement, door open/close, temperature/humidity and water leaks. In the pilot phase sensors in beds and chairs will be added. Data and alarms sent through the platform are checked by the ATC call centre operators to alert, if necessary, relatives, neighbours, and Turin Social Services to ensure follow-up of the persons.

3.1 inCASA Ethical Policy

ATC confirms its adherence to the InCASA Ethical Policy.

3.2 Ethical Approval

The protocol of the study has been submitted to the ATC public officer in charge of privacy protection. The pilot study did not need further ethical or regulatory approval since the inCASA study is observational and non-invasive.

3.3 Ethical Guideline Check List

Check list	Compliance	Comments
Privacy and Data Protection		
Is information collected in ways of which the data subject is aware?	☒	Yes
Will the information be deleted when it is no longer needed for the purpose for which it was collected?	☒	Yes
Who will have access to or use of the data collected?	☒	Only the ATC team in charge of the project and the Turin municipality Social Services staff caring for the persons will have access to or use the data collected
Will the data be transferred to or shared with others without the person's awareness?	☒	No
Has the project taken steps to ensure that persons cannot be identified from the data to be collected?	☒	Yes. The persons are identified by the devices' IDs
What assurances exist that the information collected is true and accurate?	☒	The data are collected by the devices
Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?	☒	Personal data of persons is stored in ATC management system with a secured access. Data sent through the platform can be accessed by a web portal with encryption and access control

Have measures been put in place to facilitate the person's access to his or her personal data?	☒	Not applicable for ATC pilot
Can the person whose data are collected easily rectify errors in personal data? What procedures are in place for doing so?	☒	Not applicable for ATC pilot
Surveillance		
Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?	☒	No CCTV cameras or other surveillance devices are used for the project by the ATC pilot
How and for how long will images or data be retained?	☒	Not applicable for ATC pilot
How will such images or data be used or erased?	☒	Not applicable for ATC pilot
Who will authorise the surveillance practice, whether in private homes or assisted living residences?	☒	Not applicable for ATC pilot
What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?	☒	Not applicable for ATC pilot
Autonomy		
Does the project curtail a person's right to liberty and security in any way?	☒	No
Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?	☒	Yes
Will the project use a technology to constrain a person or curtail their freedom of movement or association?	☒	No
Dignity		
Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?	☒	Yes
Is such recognition explicitly articulated in statements to those involved in or affected by the project?	☒	Yes
Does the project compromise or violate human dignity? For example, does the project involve body scanners?	☒	No
Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?	☒	No
Does the project or service or application involve implants?	☒	No
Informed Consent		
Has the project obtained the free and informed consent of those persons involved in or affected by the project?	☒	Yes
Has the person been informed of the nature, significance, implications and risks of the	☒	Yes

technology in question?		
Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?	☒	Yes
If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?	☒	Not applicable. A person unable to sign or to mark a document cannot participate to the study (exclusion criterion).
Are people aware that personal data may be collected? Are they aware of who is collecting it and why?	☒	Yes
Has the person consented to collection of his personal data?	☒	Yes
Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?	☒	Yes
If the individual is not able to give informed consent (because, for example, the person suffers from dementia) to participate in a project or to use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?	☒	Not applicable. Such a person cannot participate to the study (exclusion criterion).
Has the person had an interview with a project representative in whom he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?	☒	Yes
Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?	☒	Yes
Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?	☒	Yes
Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?	☒	Yes
Is consent given truly voluntarily? For example, does the person need to give consent in order to get a service to which there is no alternative?	☒	Yes, the consent is given truly voluntarily
Does the person have to deliberately and consciously opt out in order *not* to receive the	☒	Yes

“service”?		

Table 1: ATC Ethical Guideline Check List

3.3.1 Reporting to the Ethical Board

The data collection in ATC pilot does not raise particular ethical problem and there thus are no ethical issues to report to the Ethical Board.

4 Chorleywood Health Centre (CHC), UK

The objectives of the Chorleywood inCASA pilot are:

- To build the technical and clinical service to respond to remote patient monitoring (RPM) – health/clinical data and social/environmental data
- Evaluate the value of such a service to both the frail elderly and the clinical and social services that care for them
- Understand and measure the impact of such a service on a patient's quality of life.

Chorleywoods pre-pilot phase began in April 2011. The following provides a brief summary of progress to date.

- A subset of the Technology tested in 10 homes (2 from the target users)
  - Blood Pressure, Weight and Hub
  - Further testing carried out for: SpO2, PIR, Bed and Chair Sensor

- A number of technology challenges identified during pre-pilot phase including:
    - Battery Life
    - Pairing
    - Communications

- Target of 7 day successful and error free in each home prior to being accepted as ready for pilot phase.

- Development of the Gateway (Home Hub) has continued
  - Initial Based on Smart Meter – Pre-Pilot Phase
    - Limited number of device connections
  - Moving to hidden PC with dongle – Pilot Phase
    - Interim Solution – Speed up deployment
  - Final Solution – Pilot Phase
    - Hidden gateway
    - Allowing up to 25 device connections
    - Plug and play, fully interoperable

- The inCASA clinical protocol and evaluation methodology has been written as documented in Deliverable *D6.1inCASA European Pilot: aims, Sample, Methodology*

The Pilot Phase is due to start in March 2012. Data will be collected for a period of 6 months.

4.1 inCASA Ethical Policy

CHC confirms that it will adhere to the inCASA Ethical Policy in addition to the UK's requirements for ethical approval as defined by the Health Research authority and the Research Ethics Committee.

4.2 Ethical Approval

This project is set in two phases, the pre-pilot and pilot phase. The aim of the pre-pilot phase is to test the research protocol including:

- Project aims and objectives
- Technology
- Evaluation Methodology including questionnaires

This phase of the project does not require ethical approval.

The second phase – the Pilot Phase is classified as a clinical trial to study a novel intervention to compare interventions in clinical practice. As such this does require ethical approval.

CHC is in the process of obtaining ethical approval based on the outcomes of the pre-pilot phase. This ethical approval has been submitted to the NHS Research Ethics Committees (RECS) via the Integrated Research Application System (IRAS).

4.3 Ethical Guideline Check List

Check list	Compliance	Comments
Privacy and Data Protection		
Is information collected in ways of which the data subject is aware?	☒	Yes
Will the information be deleted when it is no longer needed for the purpose for which it was collected?	☒	Yes
Who will have access to or use of the data collected?	☒	Health Professionals and Investigator Team
Will the data be transferred to or shared with others without the person's awareness?	☒	No
Has the project taken steps to ensure that persons cannot be identified from the data to be collected?	☒	Yes
What assurances exist that the information collected is true and accurate?	☒	Data is tested and reviewed for correctness
Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?	☒	Personal Information for each of the participants will be stored in a secure database. All information concerning the project including interviews, questionnaire results, transcriptions and audio recordings both as hard copy and in electronic form will be stored in a secure locked cupboard within Chorleywood Health Centre or on the secure server
Have measures been put in place to facilitate the person's access to his or her personal data?	☒	As part of the study protocol, data will be shared with the participant on a regular basis.
Can the person whose data are collected rectify easily errors in personal data? What procedures are in place for doing so?	☒	The participant has contact numbers for the chief investigator who will amend errors in any data.
Surveillance		
Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?	☒	There are no CCTV cameras, the pilot will be using motion detectors and chair and bed sensors.
How and for how long will images or data be retained?	☒	The data will be stored for up to 2 years
How will such images or data be used or erased?	☒	All data will be erased from the server and paper data will be

		shredded.
Who will authorise the surveillance practice, whether in private homes or assisted living residences?	☒	The patient will authorise the use of sensors within the home.
What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?	☒	Not applicable
Autonomy		
Does the project curtail a person's right to liberty and security in any way?	☒	No
Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?	☒	Yes
Will the project use a technology to constrain a person or curtail their freedom of movement or association?	☒	No
Dignity		
Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?	☒	Yes
Is such recognition explicitly articulated in statements to those involved in or affected by the project?	☒	Yes
Does the project compromise or violate human dignity? For example, does the project involve body scanners?	☒	No
Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?	☒	No
Does the project or service or application involve implants?	☒	No
Informed Consent		
Has the project obtained the free and informed consent of those persons involved in or affected by the project?	☒	Yes
Has the person been informed of the nature, significance, implications and risks of the technology in question?	☒	Yes
Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?	☒	Yes
If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?	☒	Yes
Are people aware that personal data may be collected? Are they aware of who is collecting it and why?	☒	Yes
Has the person consented to collection of his	☒	Yes

personal data?		
Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?	☒	Yes
If the individual is not able to give informed consent (because, for example, the person suffers from dementia) to participate in a project or to use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?	☒	Yes
Has the person had an interview with a project representative in whom he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?	☒	Yes
Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?	☒	Yes
Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?	☒	Yes
Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?	☒	Yes
Is consent given truly voluntarily? For example, does the person need to give consent in order to get a service to which there is no alternative?	☒	Yes
Does the person have to deliberately and consciously opt out in order *not* to receive the "service"?	☒	Yes

Table 2: CHC Ethical Guideline Check List

4.3.1 Reporting to the Ethical Board

None

5 Fundación Hospital Calahorra (FHC), Spain

By December 2011, 30 patients were selected by a pulmonologist to be included in the FHC pilot according to their respective health conditions. They have been distributed in 6 groups depending on their place of residence, mainly, and COPD LOWI (1st group consists of 5 patients that live in the surrounding area of FHC, and the 6th group includes patients that live far away from the Hospital (35 to 50 km). There is also a "0" patient, who was the first selected patient to take part in our pilot; he was also the first one to test the kit by doing exercises at the Hospital and the one who provided us with a first feedback about the performance of the devices under real conditions. On January 2012 the first "kit", including a PC with touch screen, pulsioximeter and related devices, has been installed at patient's home by local specialized partners (UPICAL). The first group has already attended their Rehabilitation Consultation by Dr. Ricardo Jariod and they have also started their training period at the Hospital's Gym. In short, there are 6 patients fully involved at this point (group 1).

Please see the charts below, with details about selected patients. Due to national regulations we cannot include personal data related to health issues at this point ,and for this reason names have been deleted although code number has been included for tracking purposes. Dr. Jariod has also selected an additional group of patients that will act as a "control group" as they will not be involved in in-home activities, but only in hospital gym activities.

Finally, Edmonton Frailty Scale (proposed at a conference call held at INSERM, France, on November 2011) as well as SF-36 are currently being applied so that common data related to health & social results in inCASA's patients will be collected at FHC, too.

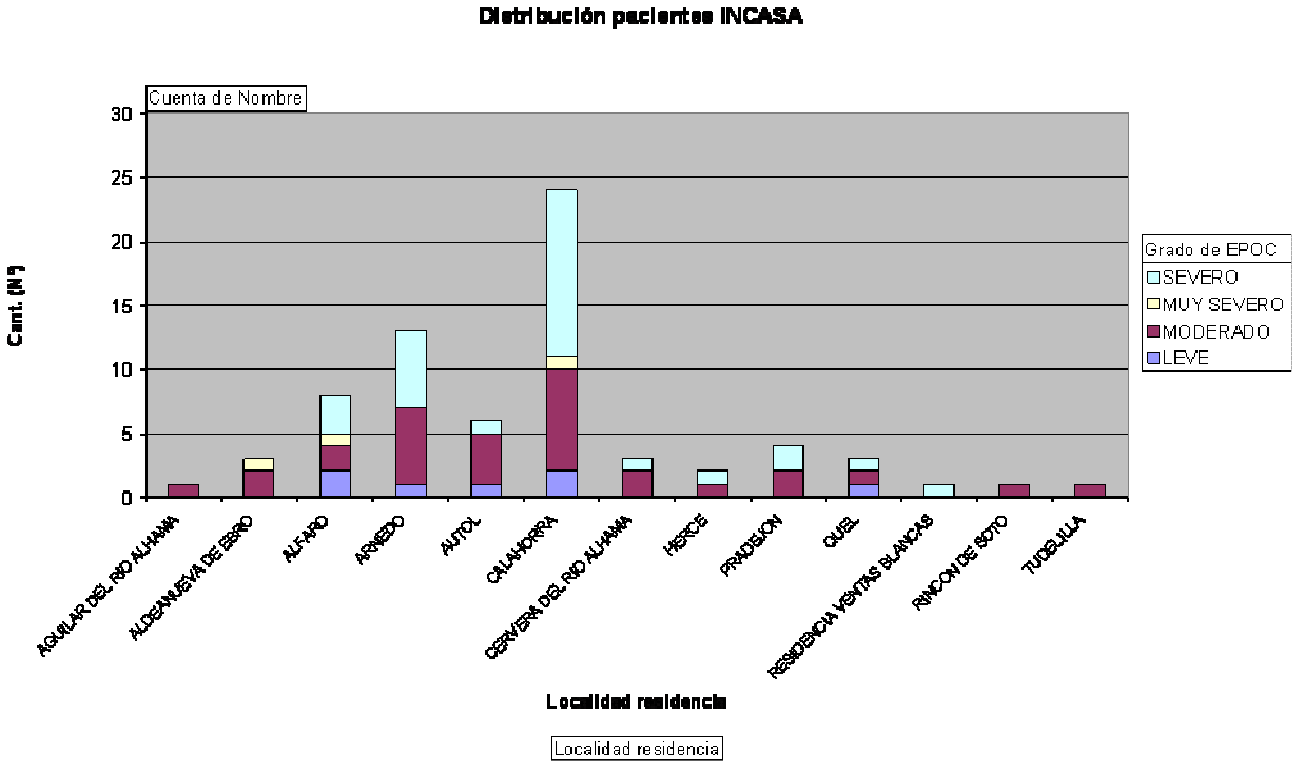

Chart 1: inCASA patients distributed by place of residence; Calahorra is the name of the city where FHC facilities are located (e.g. gym), the rest of the names are villages in the surrounding area attended by FHC where there are also patients pre-selected for the FHC pilot ("grado de EPOC" means "COPD LOWI": severe, very severe, moderate, low).

Chart 2: Nº of patients per group/place of residence

Place of residence (city-village)	Tot.		1º	2º	3º	4º	5º	6º
ALDEANUEVA DE EBRO	1	1					***X***	
ALFARO	4	4			***X***			
ARNEDO	8	8		***X (5)***		***X (3)***		
AUTOL	2	2					***X***	
CALAHORRA	7	7	***X (5)***				***X (2)***	
CERVERA DEL RIO ALHAMA	2	2						***X***
HERCE	2	2						***X***
PRADEJON	1	1	***X***					
QUEL	1	1				***X***		
RESIDENCIA VENTAS BLANCAS	1	1						***X***
RINCON DE SOTO	1	1			***X***			
TUDELILLA	1	1				***X***		
Tot.	31	31	***6***	***5***	***5***	***5***	***5***	***5***

Chart 3: Data collection (Column 1 includes Clinical record code, columns 2 & 3 – Patients' names – have been deleted due to legal regulations referring to personal data; column 5 means "age" and column 7 means "patient selected").

Nº HC	Place of residence	Age	COPD LEVEL	Selected? (S=yes)	1º	2º	3º	4º	5º	6º
65783	AGUILAR DEL RIO ALHAMA	82	MODERATE							
7590	ALDEANUEVA DE EBRO	80	MODERATE	S						
14337	ALDEANUEVA DE EBRO	68	VERY SEVERE							
105577	ALDEANUEVA DE EBRO	55	MODERATE							
73563	ALFARO	77	SEVERE	S						
13315	ALFARO	81	VERY SEVERE							
6688	ALFARO	59	LOW							
9870	ALFARO	74	SEVERE	S						
5621	ALFARO	86	MODERATE							
6196	ALFARO	67	SEVERE	S						
11938	ALFARO	67	LOW							
5872	ALFARO	74	MODERATE	S						
63392	ARNEDO	79	MODERATE	S						
48573	ARNEDO	53	MODERATE							
48549	ARNEDO	70	MODERATE	S						
61836	ARNEDO	65	SEVERE	S						
52956	ARNEDO	65	MODERATE	S						
107225	ARNEDO	59	SEVERE							
57273	ARNEDO	80	SEVERE							
50899	ARNEDO	77	SEVERE	S						
61047	ARNEDO	79	SEVERE	S						
61084	ARNEDO	78	LOW							
51832	ARNEDO	89	SEVERE							
58003	ARNEDO	75	MODERATE	S						
56995	ARNEDO	75	MODERATE	S						
12779	AUTOL	62	LOW							

25578	AUTOL	70	MODERATE	S						
32884	AUTOL	58	MODERATE							
103794	AUTOL	34	MODERATE							
36364	AUTOL	70	SEVERE	S						
43865	AUTOL	58	MODERATE							
23895	CALAHORRA	84	LOW							
28761	CALAHORRA	60	SEVERE							
31118	CALAHORRA	75	SEVERE							
33265	CALAHORRA	56	SEVERE							
22341	CALAHORRA	63	MODERATE							
41342	CALAHORRA	75	MODERATE	S						
21812	CALAHORRA	67	LOW							
33265	CALAHORRA	56	SEVERE							
32194	CALAHORRA	69	SEVERE	S	X					
70798	CALAHORRA	81	SEVERE							
33786	CALAHORRA	69	MODERATE	S	X					
41352	CALAHORRA	57	SEVERE							
90787	CALAHORRA	61	VERY SEVERE							
34274	CALAHORRA	81	MODERATE							
21204	CALAHORRA	88	MODERATE							
35660	CALAHORRA	68	SEVERE	S	X					
20857	CALAHORRA	57	SEVERE							
42320	CALAHORRA	76	SEVERE	S						
35667	CALAHORRA	78	MODERATE	S	X					
40727	CALAHORRA	77	MODERATE	S	X					
21019	CALAHORRA	83	MODERATE							
37172	CALAHORRA	59	SEVERE							
36300	CALAHORRA	64	SEVERE							
4519	CERVERA DEL RIO ALHAMA	73	SEVERE	S						
3272	CERVERA DEL RIO ALHAMA	68	MODERATE	S						
1185	CERVERA DEL RIO ALHAMA	84	MODERATE							
60717	HERCE	77	MODERATE	S						
49226	HERCE	70	SEVERE	S						
42390	PRADEJON	81	MODERATE							
43485	PRADEJON	60	SEVERE							
96700	PRADEJON	68	SEVERE	S	X					
32952	PRADEJON	63	MODERATE							
109058	QUEL	74	MODERATE	S						
61554	QUEL	80	SEVERE							
51407	QUEL	74	LOW							
65418	RESIDENCIA VENTAS BLANCAS	74	SEVERE	S						
11999	RINCON DE SOTO	68	MODERATE	S						
38033	TUDELILLA	68	MODERATE	S						
				31	6	0	0	0	0	0

Exclusion due to COPD LOWI= VERY SEVERE

Candidate to Control group due to COPD LOWI = Moderate

Selected according to COPD LOWI= MODERATE to SEVERE

5.1 inCASA Ethical Policy

FHC confirms its adherence to inCASA ethical policy.

5.2 Ethical Approval

Please see Appendix A1 and A2 for copies of FHC's letters of approval sent by CEICLAR[1]: Appendix A1 includes the initial approval of the project and Appendix B2 includes approval of our newly appointed Main Investigator for the inCASA project at FHC, Dr. Ricardo Jariod, in substitution of Dr. Jesús Castiella, according to signatures of the informed consent to be used at FHC pilot site (see Appendix A3).

5.3 Ethical Guideline Check List

Check list	Compliance	Comments
Privacy and Data Protection		
Is information collected in ways of which the data subject is aware?	☒	Yes
Will the information be deleted when it is no longer needed for the purpose for which it was collected?	☒	Yes (health related data will remain at patient's clinical record for the period of time established by national regulation).
Who will have access to or use of the data collected?	☒	Health professionals in charge of patient's needs only.
Will the data be transferred to or shared with others without the person's awareness?	☒	No, as stated in the informed consent
Has the project taken steps to ensure that persons cannot be identified from the data to be collected?	☒	Yes, following national regulations and FHC's managing system based upon ISO 27001 requirements.
What assurances exist that the information collected is true and accurate?	☒	Data will be reviewed by physicians on a weekly basis, and patients will receive a weekly visit at their home as well.
Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?	☒	Yes. According to national regulations and FHC's managing system based upon ISO 27001 requirements: ERP for clinical records at FHC, named SELENE (by HP), includes specific data security measures, complemented by other security measures derived from FHC's managing system certified by ISO 27001 specifications.
Have measures been put in place to facilitate the person's access to his or her personal data?	☒	Not applicable as SARA solution is designed to provide data to physicians and other health professionals.

[1] Please note that CEICLAR is the acronym for the Spanish regional ethical committee in charge of approvals of this type of projects, named "Comité Etico de Investigación Clínica de La Rioja" ("Committee for Ethics in Clinical Research in La Rioja" (http://www.cibir.es/cibir-investigacion/ceiclar)

Can the person whose data are collected rectify easily errors in personal data? What procedures are in place for doing so?	☒	Yes, by contacting the Admission Unit at FHC.
Surveillance		
Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?	☒	Not applicable to FHC pilot site (no cameras).
How and for how long will images or data be retained?	☒	Not applicable to FHC pilot site (no cameras).
How will such images or data be used or erased?	☒	Not applicable to FHC pilot site (no cameras).
Who will authorise the surveillance practice, whether in private homes or assisted living residences?	☒	Not applicable to FHC pilot site (no cameras).
What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?	☒	Not applicable to FHC pilot site (no cameras).
Autonomy		
Does the project curtail a person's right to liberty and security in any way?	☒	No
Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?	☒	Yes, it respects rights of disabled persons when applicable.
Will the project use a technology to constrain a person or curtail their freedom of movement or association?	☒	No
Dignity		
Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?	☒	Yes
Is such recognition explicitly articulated in statements to those involved in or affected by the project?	☒	Yes (see Ethical policy).
Does the project compromise or violate human dignity? For example, does the project involve body scanners?	☒	No
Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?	☒	No. It only includes the use of technology at home for a period of time that allows FHC to check if they are appropriate for each patient.
Does the project or service or application involve implants?	☒	No
Informed Consent		
Has the project obtained the free and informed consent of those persons involved in or affected by the project?	☒	Yes
Has the person been informed of the nature, significance, implications and risks of the	☒	Yes

technology in question?		
Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?	☒	Yes
If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?	☒	Not applicable to selected patients at FHC pilot site.
Are people aware that personal data may be collected? Are they aware of who is collecting it and why?	☒	Yes
Has the person consented to collection of his personal data?	☒	Yes
Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?	☒	Yes
If the individual is not able to give informed consent (because, for example, the person suffers from dementia) to participate in a project or to use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?	☒	Not applicable to selected patients at FHC pilot site.
Has the person had an interview with a project representative in whom he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?	☒	Yes (it has been conducted by the physician selected as project leader at FHC pilot site)
Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?	☒	Yes (informed consent was adapted to this specific purpose according to CEICLAR's recommendations).
Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?	☒	Yes
Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?	☒	Yes
Is consent given truly voluntarily? For example, does the person need to give consent in order to get a service to which there is no alternative?	☒	It has been given freely and voluntarily.
Does the person have to deliberately and consciously opt out in order *not* to receive the	☒	No, proactive consent is requested.

"service"?		

Table 3: FHC Ethical Guideline Check List

5.3.1 Reporting to the Ethical Board

In 2008, FHC applied for independent certification of its information security management system according to ISO 27001 and the certification has been recently renewed. Furthermore, FHC is committed to pass an external legal audit on aspects directly related to data protection due to national regulations[2] (last audit was evaluated positively in September 2011). Although there is no evidence of specific needs for FHC's participation in the inCASA project, according to these both voluntary and compulsory regulations and requirements at present, a review of its implications should be considered to be taken during inCASA deployment, specifically those potentially derived from ISO 27799:2008 (Health informatics -- Information security management in health using ISO/IEC 27002).

[2] LEY ORGÁNICA 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal (BOE nº 298, de 14 de diciembre de 1999). Source: http://www.boe.es/boe/dias/1999/12/14/pdfs/A43088-43099.pdf

6 Institut National de la Santé et de la Recherche Medicale (INSERM), France

The pre-pilot phase started in November 2011. In January 2012, five patients had been recruited for the study. The inCASA platform was installed at home during the inclusion period. The patients used it every day for body weight measurement and symptoms assessment according to the MD Anderson Symptom Inventory (MDASI). Data sent through the platform are checked by the medical staff to ensure follow-up of the patients.

6.1 inCASA Ethical Policy

INSERM confirms its adherence to the inCASA Ethical Policy.

6.2 Ethical Approval

The protocol of the study has been submitted to the Clinical Research Unit of INSERM. The commission concluded on May 17th 2011 that the pilot study did not need further ethical or regulatory approval since the inCASA study is observational and non-invasive (see letter in Appendix B). The study is being declared to the French National Commission for Data Protection (CNIL).

6.3 Ethical Guideline Check List

Check list	Compliance	Comments
Privacy and Data Protection		
Is information collected in ways of which the data subject is aware?	☒	Yes
Will the information be deleted when it is no longer needed for the purpose for which it was collected?	☒	Data is stored by the unit for ten years
Who will have access to or use of the data collected?	☒	Only the INSERM team in charge of the project and the health staff caring for the patient will have access to or use the data collected
Will the data be transferred to or shared with others without the person's awareness?	☒	No
Has the project taken steps to ensure that persons cannot be identified from the data to be collected?	☒	Yes. The patients are identified by a code number
What assurances exist that the information collected is true and accurate?	☐	None. The data are collected by the patients. We cannot check if this is actually the case
Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?	☒	Personal data of patients is stored in the hospital management system with a secured access. Data sent through the platform can be accessed by a web portal with encryption and access control
Have measures been put in place to facilitate the	☒	Patients can access their

person's access to his or her personal data?		personal data by contacting their medical doctor
Can the person whose data are collected rectify easily errors in personal data? What procedures are in place for doing so?	☒	Errors in personal data can be easily rectified thanks to the data management system of the hospital
Surveillance		
Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?	☒	No CCTV cameras or other surveillance devices are used for the project by the INSERM pilot
How and for how long will images or data be retained?	☒	Not applicable for INSERM pilot
How will such images or data be used or erased?	☒	Not applicable for INSERM pilot
Who will authorise the surveillance practice, whether in private homes or assisted living residences?	☒	Not applicable for INSERM pilot
What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?	☒	Not applicable for INSERM pilot
Autonomy		
Does the project curtail a person's right to liberty and security in any way?	☒	No
Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?	☒	Yes
Will the project use a technology to constrain a person or curtail their freedom of movement or association?	☒	No
Dignity		
Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?	☒	Yes
Is such recognition explicitly articulated in statements to those involved in or affected by the project?	☒	Yes
Does the project compromise or violate human dignity? For example, does the project involve body scanners?	☒	No
Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?	☒	No
Does the project or service or application involve implants?	☒	No
Informed Consent		
Has the project obtained the free and informed consent of those persons involved in or affected by the project?	☒	Yes

Has the person been informed of the nature, significance, implications and risks of the technology in question?	☒	Yes
Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?	☒	Yes
If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?	☒	Not applicable. A person unable to sign or to mark a document cannot participate to the study (exclusion criterion).
Are people aware that personal data may be collected? Are they aware of who is collecting it and why?	☒	Yes
Has the person consented to collection of his personal data?	☒	Yes
Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?	☒	Yes
If the individual is not able to give informed consent (because, for example, the person suffers from dementia) to participate in a project or to use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?	☒	Not applicable. Such a person cannot participate to the study (exclusion criterion).
Has the person had an interview with a project representative in whom he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?	☒	Yes
Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?	☒	Yes
Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?	☒	Yes
Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?	☒	Yes
Is consent given truly voluntarily? For example, does the person need to give consent in order to get a service to which there is no alternative?	☒	Yes, the consent is given truly voluntarily

Does the person have to deliberately and consciously opt out in order *not* to receive the "service"?	☒	No. The patients have to express his interest to participate in the study

Table 4: INSERM Ethical Guideline Check List

6.3.1 Reporting to the Ethical Board

The system used in the pre-pilot phase does not allow adequate telemonitoring of the patients. Parameters are not displayed in order to properly view changes over time. Thus, the platform does not yet allow quick visualization of a change in the patient condition. This raises an ethical issue for prolonging the pre-pilot phase since we are aware that their follow-up cannot involve the nursing staff as planned for the pilot phase of the project. The requested changes are in the process of being implemented by the technical partners, following the technical meeting of January 12th 2012.

7 Konstantopouleio General Hospital of Nea Ionia (KGHNI), Greece

The pre-pilot phase started in October and was concluded in December 2011. Three (3) patients participated in the pre-pilot. In January 2012, additional patients have been recruited for the main pilot phase. The inCASA platform was installed at home during the inclusion period. The patients used it every day for body weight measurement. Data sent through the platform were checked by the medical staff to ensure follow up of the patients, and selected members of the technical team of NTUA for verifying the proper operation of the inCASA platform.

7.1 inCASA Ethical Policy

KGHNI confirms its adherence to the inCASA Ethical Policy.

7.2 Ethical Approval

The protocol of the pilot has been submitted and accepted by the local Ethical Committee of the hospital. The board concluded that the pilot study did not need further ethical or regulatory approval since the inCASA study is observational and non-invasive (please see Appendix C).

7.3 Ethical Guideline Check List

Check list	Compliance	Comments
Privacy and Data Protection		
Is information collected in ways of which the data subject is aware?	☒	Yes
Will the information be deleted when it is no longer needed for the purpose for which it was collected?	☒	Data will be deleted after the Project's evaluation end
Who will have access to or use of the data collected?	☒	KGHNI operators, nurses and doctors as long as NTUA system administrators
Will the data be transferred to or shared with others without the person's awareness?	☒	No, as stated in the informed consent
Has the project taken steps to ensure that persons cannot be identified from the data to be collected?	☒	Yes. The patients are identified by a code number. The mapping of the code number with the actual patient name will be stored in KGHNI internal files
What assurances exist that the information collected is true and accurate?	Partially	Some basic system validations and a 1-2 weeks period data review performed by the doctors in cooperation with the patients
Has the project taken measures to ensure protection of personal data, e.g., by means of encryption and/or access control? If so, what are they?	☒	Data are available through a web portal providing access-control. Only KGHNI authorized personnel will be able to access the Web Portal.
Have measures been put in place to facilitate the person's access to his or her personal data?	☒	Telehealth data (vital signs measurements) are available on the local PC of each user through the SARA client application. As far as Telecare

		data are concerned (Power Consumption, Chair Permanence and Movement indicator) the patient should contact their doctor
Can the person whose data are collected rectify easily errors in personal data? What procedures are in place for doing so?	Partially	The person must contact the KGHNI doctors who will forward the issue to technicians
Surveillance		
Have any signs or other notifications been made to alert people to the presence of CCTV cameras or other surveillance devices?	☒	No CCTV cameras or other surveillance devices are used for the project by the KGHNI pilot.
How and for how long will images or data be retained?	☒	Not applicable for KGHNI pilot
How will such images or data be used or erased?	☒	Not applicable for KGHNI pilot
Who will authorise the surveillance practice, whether in private homes or assisted living residences?	☒	Not applicable for KGHNI pilot
What measures will be put in place to avoid abuses where, for example, surveillants watch others engaged in behaviour that generally accepted social norms would regard as intimate or private?	☒	Not applicable for KGHNI pilot
Autonomy		
Does the project curtail a person's right to liberty and security in any way?	☒	No
Does the project recognise and respect the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community?	☒	Yes
Will the project use a technology to constrain a person or curtail their freedom of movement or association?	☒	No
Dignity		
Does the project recognise and respect the right of citizens to lead a life of dignity and independence and to participate in social and cultural life?	☒	Yes
Is such recognition explicitly articulated in statements to those involved in or affected by the project?	☒	Yes
Does the project compromise or violate human dignity? For example, does the project involve body scanners?	☒	No
Does the project require citizens to use a technology that marks them in some way as cognitively or physically disabled?	☒	No
Does the project or service or application involve implants?	☒	No
Informed Consent		
Has the project obtained the free and informed	☒	Yes

consent of those persons involved in or affected by the project?		
Has the person been informed of the nature, significance, implications and risks of the technology in question?	☒	Yes. The technology used does not imply any particular risk.
Has such consent been evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent?	☒	Yes
If the person is unable to sign or to mark a document so as to indicate his consent, has his consent been given orally in the presence of at least one witness and recorded in writing?	☒	Not applicable.
Are people aware that personal data may be collected? Are they aware of who is collecting it and why?	☒	Yes, as it is stated in the informed consent
Has the person consented to collection of his personal data?	☒	Yes, by signing the informed consent
Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?	Partially	The informed consent analyses the use for which data are to be collected, how the data are to be collected and details of who will have access to the data which are the sensitive parameters of the study.
If the individual is not able to give informed consent (because, for example, the person suffers from dementia) to participate in a project or to use of a technology, have the project representatives consulted with close relatives, a guardian with powers over the person's welfare or professional carers? Has written consent been obtained from the patient's legal representative and his doctor?	☒	Not applicable.
Has the person had an interview with a project representative in whom he has been given the opportunity to understand the objectives, risks and inconveniences of the project or research activity and the conditions under which it is to be conducted?	☒	Yes. All patients of the inCASA KGHNI pilot are familiar with the KGHNI doctors and, thus, are familiar with the project goals and procedures.
Has the person been informed of his right to withdraw from the project or trial at any time, without being subject to any resulting detriment or the foreseeable consequences of declining to participate or withdrawing?	☒	Yes, clearly written in the consent
Has the project ensured that persons involved in the project have given their informed consent, not only in relation to the aims of the project, but also in relation to the *process* of the research, i.e., how data will be collected and by whom, where it will be collected, and what happens to the results?	☒	Yes
Are persons involved in or affected by the project able to withdraw from the project *and* to withdraw their data at any time right up until publication?	☒	Yes

Is consent given truly voluntarily? For example, does the person need to give consent in order to get a service to which there is no alternative?	☒	Yes
Does the person have to deliberately and consciously opt out in order *not* to receive the "service"?	☒	No

Table 5: KGHNI Ethical Guideline Check List

7.3.1 Reporting to the Ethical Board

No comments or issues to report.

8 Conclusion

In accordance with national regulations, all of the five inCASA pilots have obtained the necessary ethical approval. Prior to their kick-off, all the inCASA pilots had submitted their protocols of study to their relevant national ethical authorities. According to national regulations, three of the pilots, ATC, INSERM and KGHNI, do not need any further and formal ethical approval since their research is defined as non-invasive. The CHC pilot in this first stage (pre-pilot stage) does not require ethical approval. Approval for the forthcoming second phase, the Pilot Phase, has been submitted to the relevant authority. The FHC has applied for and been granted ethical approval from the relevant authority.

All five pilots confirm their adherence to the project's Ethical Policy as defined in deliverable *D2.3 Country national policies and ethical package*.

All five pilots have filled out the Ethical Check List and commented on the issues as appropriate. Some issues will require further discussion at the forthcoming Ethical Board meeting on 2 February 2012. These issues are:

- What assurances exist that the information collected is true and accurate?
- Can the person whose data are collected easily rectify errors in personal data? What procedures are in place for doing so?
- Does the consent outline the use for which data are to be collected, how the data are to be collected, instructions on how to obtain a copy of the data, a description of the mechanism to correct any erroneous data, and details of who will have access to the data?

Finally, INSERM raises an additional ethical issue related to the technological solution, namely that parameters are not displayed in order to properly view changes over time. INSERM thus suggests that it may be necessary to extend the pre-pilot phase. This technological issue was raised at the technical meeting on 12 January 2012 and a solution has been proposed. The necessary improvements of the web portal are expected by mid/end February 2012.

Appendix A1: FHC Letter of Approval

Gobierno de La Rioja
www.larioja.org

Rioja Salud
FUNDACIÓN

Fundación Rioja Salud
Entrada N.º.....
- 6 OCT. 2011
Salida N.º 106

Comité Ético de Investigación Clínica
de La Rioja (CEICLAR)

HOSPITAL CALAHORRA Gobierno de La Rioja Salud
18 OCT. 2011
ENTRADA Nº 1160

(Para Proyectos de Investigación)

DICTAMEN DEL COMITÉ ETICO DE INVESTIGACIÓN CLÍNICA DE LA RIOJA

D. José Ignacio Torroba Terroba.
Secretario del Comité Ético de Investigación Clínica de La Rioja

CERTIFICA

Una vez evaluado el Proyecto de Investigación:

Titulo:
"Proyecto INCASA" **(Ref. CEICLAR PI nº 84).**

Persona de contacto:
FUNDACIÓN HOSPITAL DE CALAHORRA
A/A: Pelayo Benito
Carretera de Logroño S/N.
26500 Calahorra – (La Rioja)

que se va a llevar a cabo en el centro **Fundación Hospital de Calahorra** por Jesús Castiella Herrero Servicio de Medicina interna como investigador principal.

El Comité Ético de Investigación Clínica de La Rioja (CEICLAR) manifiesta en reunión del 29-09-2011 que no se han encontrado aspectos metodológicos, éticos y legales que impidan su realización; por lo que se emite un **DICTAMEN FAVORABLE.**

Lo que firmo en Logroño a 06 de Octubre de 2011

Firmado:

El Secretario en Funciones del CEICLAR
D. Eduardo Mirpuri Merino

Edificio CIBIR Piqueras 98 - 3ª Planta . 26006 · Logroño · La Rioja ·
Tel.: 941 278855 Ext 89867· Fax.: 941 278 887 secretaria.ceic@larioja.org

Appendix A2: FHC Letter of Approval

Approval of FHC's newly appointed Main Investigator for inCASA project at FHC, Dr. Ricardo Jariod.

Gobierno de La Rioja
www.larioja.org

Rioja Salud
FUNDACIÓN

Fundación Rioja Salud
Entrada N.º
25 NOV. 2011
Salida N.º 125

Comité Ético de Investigación Clínica de La Rioja (CEICLAR)

DICTAMEN DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA DE LA RIOJA para modificación de protocolo de estudios de investigación

D. José Ignacio Torroba Terroba
Secretario del Comité Ético de Investigación Clínica de La Rioja

CERTIFICA

Que este Comité ha evaluado la propuesta del promotor relativa a la modificación:

PROMOTOR:
Carlos Piserra Bolaños en su calidad de director y representante legal de FUNDACIÓN HOSPITAL DE CALAHORRA

perteneciente al estudio:
Titulo:
"Proyecto INCASA" **(Ref. CEICLAR PI nº 84).**

FUNDACIÓN HOSPITAL DE CALAHORRA
Coordinador Unidad Calidad
Pelayo Benito García
Carretera de Logroño S/N.
26500 Calahorra – (La Rioja)

que se va a llevar a cabo en el centro Fundación Hospital de Calahorra por D. Ricardo Jariod Gaudes, como investigador principal en sustitución de D. Jesús Castiella Herrero .

emite un **DICTAMEN FAVORABLE** para la realización de la modificación al estudio en los centros pertinentes.

Lo que firmo en Logroño a 25 de Noviembre de 2011

Firmado:

El Secretario del CEICLAR

Edificio CIBIR Piqueras 98 - 3ª Planta . 26006 · Logroño · La Rioja ·
Tel.: 941 278855 Ext 89867· Fax.: 941 278 887 secretaria.ceic@larioja.org

Appendix A3: FHC Informed Consent Form

MODELO DE HOJA DE INFORMACIÓN AL PACIENTE

TÍTULO DEL ESTUDIO: Red de servicios integral para la mejora de la autonomía de las personas mayores europeas: tele monitorización de pacientes con EPOC

INVESTIGADOR PRINCIPAL: Ricardo Jariod Gaudes**,** Médico especialista en rehabilitación y Gestor de Proceso de rehabilitación de Fundación Hospital Calahorra, rjariod@riojasalud.es

CENTRO: Fundación Hospital Calahorra.

INTRODUCCIÓN

Nos dirigimos a usted para informarle sobre un proyecto de I+D internacional en el que se le invita a participar. El proyecto ha sido aprobado por el Comité Ético de Investigación Clínica correspondiente (CEICLAR –Comité Ético de Investigación Clínica de La Rioja-[3]) en su reunión de fecha 29 de septiembre de 2011

Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este proyecto. Para ello lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno.

PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su tratamiento.

DESCRIPCIÓN GENERAL DEL ESTUDIO:

Consiste en facilitar al paciente una serie de ejercicios de rehabilitación que se realizarán en sus casas y cuya realización será monitorizada desde el Hospital por parte de profesionales sanitarios cualificados. El plan de ejercicios y todo el equipamiento será proporcionado e instalado por Fundación Hospital Calahorra.

La duración de cada uno de los pilotajes en los pacientes participantes será de uno a tres meses.

El paciente participante formará parte de un grupo de entre 20 y 30 personas que deberán acudir a las reuniones formativas que se programen periódicamente si no hubiera causa justificada que se lo impida.

BENEFICIOS Y RIESGOS DERIVADOS DE SU PARTICIPACIÓN EN EL ESTUDIO.

Los beneficios que se esperan al término del proyecto son una mejora de la calidad de vida del paciente al reducir en gran medida los desplazamientos al propio Hospital así como facilitar un incentivo para realizar de forma continuada ejercicios ajustados a sus necesidades como paciente crónico.

Las técnicas propuestas en el estudio no conllevan ningún riesgo potencial para su salud.

TRATAMIENTOS ALTERNATIVOS.

En el caso de que el paciente no desee participar, podrá en todo caso seguir con el tratamiento en las mismas condiciones que lo está recibiendo hasta la fecha.

[3] http://www.cibir.es/cibir-investigacion/ceiclar

CONFIDENCIALIDAD

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal. De acuerdo a lo que establece la legislación mencionada, usted puede ejercer los derechos de acceso, modificación, oposición y cancelación de datos, para lo cual deberá dirigirse a su médico del estudio.

Los datos recogidos para el estudio estarán identificados mediante un código y solo su médico del estudio/colaboradores debidamente autorizados podrá relacionar dichos datos con usted y con su historia clínica. Por lo tanto, su identidad no será revelada a persona alguna salvo en caso de urgencia médica o requerimiento legal.

Sólo se transmitirán a terceros y a otros países los datos recogidos para el estudio que en ningún caso contendrán información que le pueda identificar directamente, como nombre y apellidos, iniciales, dirección, nº de la seguridad social, etc. En el caso de que se produzca este cesión, será para los mismos fines del estudio descrito y garantizando la confidencialidad como mínimo con el nivel de protección de la legislación vigente en nuestro país.

El acceso a su información personal quedará restringido al médico del estudio/colaboradores, debidamente autorizados, autoridades sanitarias (Agencia Española del Medicamento y Productos Sanitarios), Comunidades Autónomas (inspección), al Comité Ético de Investigación Clínica y personal autorizado por el promotor, cuando lo precisen para comprobar los datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

COMPENSACIÓN ECONÓMICA

Los pacientes objeto del estudio no tendrán que pagar por ninguna actividad que se realice en este ni tampoco recibirán compensación económica por su asistencia.

OTRA INFORMACIÓN RELEVANTE

Si usted decide retirar el consentimiento para participar en este proyecto, ningún dato nuevo será añadido a la base de datos y podrá exigir la destrucción de todas los datos previamente retenidos.

También debe saber que puede ser excluido del estudio si el promotor o los investigadores del estudio lo consideran oportuno, ya sea por motivos de seguridad, por cualquier acontecimiento adverso que se produzca por el tratamiento en estudio o porque consideren que no está cumpliendo con los procedimientos establecidos. En cualquiera de los casos, usted recibirá una explicación adecuada del motivo que ha ocasionado su retirada del estudio.

Al firmar la hoja de consentimiento adjunta, se compromete a cumplir con los procedimientos del estudio que se le han expuesto.

Cuando acabe su participación recibirá el mejor tratamiento disponible y que su médico considere el más adecuado para su enfermedad, pero es posible que no se le pueda seguir monitorizando a distancia. Por lo tanto, ni el investigador ni el promotor adquieren compromiso alguno de mantener dicho tratamiento fuera de este estudio.

DATOS DE CONTACTO
Ricardo Jariod Gaudes.
Correo electrónico: rjariod@riojasalud.es

CONSENTIMIENTO:

Código del Estudio:

Yo (nombre y apellidos)

……

He leído la hoja de información que se me ha entregado.

He podido hacer preguntas sobre el estudio.

He recibido suficiente información sobre el estudio.

He hablado con:
……

(nombre del investigador)

Comprendo que mi participación es voluntaria.

Comprendo que puedo retirarme del estudio:
1º.- Cuando quiera.
2º.- Sin tener que dar explicaciones.
3º.- Sin que esto repercuta en mis cuidados médicos.

- Presto libremente mi conformidad para participar en el estudio y doy mi consentimiento para el acceso y utilización de mis datos en las condiciones detalladas en la hoja de información.

☐ SÍ
☐ NO

Firma del paciente:

Nombre:
Fecha:

Firma del investigador:

Nombre:
Fecha:

Este documento se firmará por duplicado quedándose una copia el investigador y otra el paciente.

REVOCACIÓN del CONSENTIMIENTO:

Código del Estudio:

Yo (nombre y apellidos)

……

Revoco el consentimiento otorgado a D. ……

para participar en el estudio en el que había sido incluido.

Firma del paciente:

Firma del investigador:

Nombre:
Fecha:

Nombre:
Fecha:

Este documento se firmará por duplicado quedándose una copia el investigador y otra el paciente.

Appendix B: INSERM Letter of Ethical Approval

Instituts thématiques

Inserm

Institut thématique
Santé publique
Pôle Recherche Clinique

Institut national
de la santé et de la recherche médicale

Nos réf. : SG/DGa/2011-181
Réf CPS : # n°18/2011
Dossier suivi par Sonia GUEGUEN
☎ : 01 44 23 61 05
📠 : 01 44 23 67 10
@ : sonia.gueguen@inserm.fr

Docteur Francis LEVI
INSERM U776
"Rythmes Biologiques et Cancers"
Porte 66
Hôpital Paul Brousse
14 avenue Paul Vaillant Couturier
94807 Villejuif Cedex

Paris, le 17 mai 2011

Objet : Accord de principe à se porter responsable du projet

Cher Monsieur,

Vous avez demandé à l'Inserm de se déclarer promoteur du projet de recherche cité en objet.

Après analyse il apparaît que le projet que vous avez présenté à l'Inserm ne relève pas des dispositions relatives aux recherches biomédicale (notamment les articles L .1121-1 et suivants du Code de la Santé Publique) L'Inserm ne se portera donc pas promoteur de cette recherche au sens de l'article L. 1121-1d u Code de la Santé Publique.

Néanmoins nous vous informons que l'Inserm se porte responsable de ce projet au titre des lois Informatique et Libertés et des lois de Bioéthique. Dans ce cadre le Pôle de Recherche Clinique de l'Institut Santé Publique de l'Inserm vous propose un accompagnement dans les démarches de mise en place et de suivi réglementaire. Pour toutes questions concernant ces démarches vous voudrez bien prendre contact avec Béatrice Barraud (beatrice.barraud@inserm.fr, 01 44 23 67 29).

Je vous prie d'agréer, Cher Monsieur, l'expression de mes sincères salutations.

Par délégation du Président Directeur Général de l'Inserm,

Claire Levy-Marchal
Coordinatrice du Pôle Recherche Clinique

Copie : Béatrice Barraud, Mission Réglementation et Qualité en Recherche Clinique
Laurence PARMANTIER, DR de Paris XI

Inserm
101, rue de Tolbiac 75654 Paris Cedex 13
Tél. +33 (0)1 44 23 60 00 Fax +33 (0)1 45 85 68 56

République française

Appendix C: KGHNI Letter of Ethical Approval

ΑΠΟΣΠΑΣΜΑ ΔΙΟΙΚΗΤΙΚΟΥ ΣΥΜΒΟΥΛΙΟΥ ΤΗΣ 12 ης ΣΥΝΕΔΡΙΑΣΗΣ ΤΗΣ
29 Δεκεμβρίου 2011

Θέμα : Γ1 Έγκριση για την συμμετοχή της Καρδιολογικής Κλινικής στο πρόγραμμα της Ευρωπαϊκής Ένωσης in CASA.

Η Πρόεδρος του Διοικητικού Συμβουλίου του Νοσοκομείου παρουσιάζει την εισήγησή σχετικά με το θέμα (αριθμ. πρωτ.474/14-12-2011) η οποία αναφέρει τα εξής:

«Το Επιστημονικό Συμβούλιο, αφού έλαβε γνώση :
1ον : της αίτησης με αρ. πρωτ. 336/16.9.2011 του κ. Σωτήριου Πατσιλινάκου Συντονιστή Διευθυντή του Καρδιολογικού Τμήματος, για έγκριση συμμετοχής της Καρδιολογικής Κλινικής στο πρόγραμμα της Ευρωπαϊκής Ένωσης in CASA του οποίου η χρηματοδότηση και επίβλεψη θα γίνεται από την 1η ΥΠΕ.
2ον : Το έντυπο συγκατάθεσης (informed consent) των συμμετεχόντων σ' αυτό το πρόγραμμα
3ον : Τις βεβαιώσεις των επιστημονικών υπευθύνων της ερευνητικής μελέτης κ.κ. Σ. Πατσιλινάκου Συντονιστή Διευθυντή Καρδιολογικού Τμήματος και Αθανάσιου Αναδιώτη Επιμ. Β' Καρδιολόγου, ότι η υλοποίηση της δεν προκαλεί οικονομική επιβάρυνση στο Νοσοκομείο.
4ον : Τη σύμφωνη έγγραφη έγκριση της Επιτροπής Έρευνας
Ομόφωνα συμφωνεί
Και εγκρίνει την συμμετοχή της Καρδιολογικής Κλινικής του Νοσοκομείου μας στο πρόγραμμα της Ευρωπαϊκής Ένωσης in CASA καθώς και το έντυπο συγκατάθεσης (informed consent) των συμμετεχόντων σ' αυτό, εφ' όσον οικονομικά δεν θα επιβαρύνει το Νοσοκομείο και αφού τηρηθούν όλες οι διαδικασίες της πιο πάνω Έρευνας, σύμφωνα με την διακήρυξη του Ελσίνκι, τις αρχές της Ορθής Κλινικής Πρακτικής (GCP), τους Κανονισμούς της χώρας και της Παγκόσμιας Οργάνωσης Υγείας, για ερευνητικές μελέτες.
Παρακαλούμε για τις δικές σας ενέργειες.»

Το Δ.Σ. αφού έλαβε υπόψη

Την εισήγηση της Προέδρου του Διοικητικού Συμβουλίου του Νοσοκομείου και κατόπιν διαλογικής συζήτησης

Ομόφωνα αποφασίζει

- ✓ Εγκρίνει την συμμετοχή της Καρδιολογικής Κλινικής του Νοσοκομείου μας στο πρόγραμμα της Ευρωπαϊκής Ένωσης in CASA καθώς και το έντυπο συγκατάθεσης (informed consent) των συμμετεχόντων σ' αυτό, εφ' όσον οικονομικά δεν θα επιβαρύνει το Νοσοκομείο και αφού τηρηθούν όλες οι διαδικασίες της πιο πάνω Έρευνας, σύμφωνα με την διακήρυξη του Ελσίνκι, τις αρχές της Ορθής Κλινικής Πρακτικής (GCP), τους Κανονισμούς της χώρας και της Παγκόσμιας Οργάνωσης Υγείας, για ερευνητικές μελέτες.

Το Δ.Σ. θεωρεί ομόφωνα επικυρωμένα τα πρακτικά της Συνεδρίασης αυτής όσον αφορά την ανωτέρω απόφασή του.

Η Πρόεδρος του Δ.Σ.

Όλγα Μπαλαούρα

Ακριβές απόσπασμα
Η Γραμματέας του Δ.Σ.

Νεκταρία Καμαριανάκη