Assisting Carers for CooperativE Services to Seniors		
	WP	WP3 Test- Ethic, privacy and security issues
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D3.1

Title

Ethical Rules and Ethical Committee

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1 Introduction

An ethical perspective has relevance and can be applied at all levels in the processes which determine whether and how technologies come to be used to support independent living and homecare for older people. Moreover, ethics have importance for researchers who are developing and testing technologies, and for designers who are defining their features and functions.
Generally, in research it is necessary to protect participants personal data and specifically, in this project to take into account the special characteristics of the sample.
Considering diversity in law and in the subjects that will follow the trial the ACCESS Consortium has agreed that the most effective approach is to have a different Ethical Committee in each country running the experimentation.
Therefore this document describes the ethical committee in Italy, France and Belgium with rules and other details related to the topic.

2 Ethical Committee in Italy

The Italian partner "Centro Regionale Alzheimer - Policlinico Universitario di Roma Tor Vergata" being an hospital has an official Ethical Committee in place. The Policlinico's Committee has been formally asked if it would be available to respond to possible questions and issues connected to the project and its activities. Its answered has been affirmative therefore the Italian partners will run through this committee any potential question that may require an independent approval.

The Ethical ACCESS important points relate to.

1. Freedom to decide to participate to the experimentation of elderly patients and of their caregivers (formal or informal);
2. Privacy: data protection of personal and medical information;
3. Data security: secure data storage and secure connection for data transfer;
4. Rules: define rules to provide medical, social and care services through the software platform;
5. Medical-legal responsibility of the healthcare caregiver.

2.1 Freedom to decide

The participants to the ACCESS project trial will be selected randomly from those in care by "Centro Regionale Alzheimer – University of Rome – Tor Vergata". They will be correctly and promptly informed about the objectives, method, processes and criteria of the personal and sensible data collection during the entire trial phase of the ACCESS project in order to make an informed decision about participation to
Each participant and/or his/her caregiver (formal or informal) will sign an "Informed Consent" form prepared by the researcher of CAR, it will be in place for the duration of the trial phase.
Each participant and/or his/her caregiver (formal or informal) will be able, at any point in time, to withdraw from the participation to the ACCESS project.

2.2 Privacy and personal data protection

The Italian law that guarantees and protects personal data is: D.lgs. 30 giugno 2003 n° 196 « Codice in materia di protezione dei dati personali".
According to this law, the data will be treated respecting the individual and freedom rights of the people involved and of their dignity, with special reference to privacy, identity and data protection rights.
All information provided by the participants involved in the project that will be considered «sensible data », including personal data used to identify patient health status, will be used only for project activities related to medical tasks: participants name will not be made public or divulged and each person will be protected by high privacy (art.7 Dlgs 196/2003) and it will not be possible to identify him/her for activities beyond the scope of the ACCESS project.

2.3 Storage data and connection security

The software company responsible for the storage and transmission of data (Liferesult srl in Italy) and the responsible of the data treatment CAR (Centro Regionale Alzheimer) are obliged to inform about all in all details about the objectives, method, processes and criteria of the personal and sensible data treatment and use and they must make sure the users have well understood all points and aspects.
All passwords used by local researchers will not be shared with external researcher or other external party external outside the project consortium. The names of the users will be neither used nor published unless the partner has obtained consent by the user. All personal data will be treated as confidential data (art. 13 D.Lgs. 196/2003). After the end of the survey, all data will be coded in order to avoid any possibility to identify the person, data will be traceable only through a code.
The owner of the data archiving and transmission processes will have to put in place security measure to guarantee maximum reliability and integrity of transmitted data through the telecommunication support.

2.4 Rules to be adopted for the communication of medical, health and social information using telecommunication system

The owner of the medical treatment CAR (Centro Regionale Alzheimer) defines the rules for the recording and archiving of registry, social, health data, bio-images and other patient documents required during the ACCESS trial, following the rules of the Italian healthcare public institute SSN (Servizio Sanitario Nazionale). SSN establishes the rules to be followed when providing remote care assistance and monitoring of some biometric parameter as planned in the ACCESS experimentation.

2.5 Medical and Legal responsibilities of healthcare and medical personnel

All medical and legal responsibilities for each healthcare and medical assistance intervention toward a patient and his/her formal or informal caregiver participating to the ACCESS trial lays with CAR (Centro Regionale Alzheimer).
Each healthcare and medical assistance intervention remotely executed toward a patient and/or his/her formal or informal caregiver will undergo a validation process by the healthcare responsible

personnel. The responsible person must be somebody known by the patient and/or his/her caregiver.

3 Ethical Committee in France

In France partners have no official ethical committee. Therefore they have to work to put together an independent committee with members outside their institutes and company.
The French partners have put in place a set of rules that will govern the activities of the ethical committee.

3.1 Ethical Committee members

The members of the French Ethical Committee are:
-3 managers coming from the internal Adessadomicile network (Presidents of associations or entities General Manager)
-CNAV's représentative
-Fondation de France 's représentative

Adessadomicile decided to create this Committee with two major external partners which have legitimity for our topics.

CNAV (Caisse Nationale Assurance Vieillesse) is the French National reference for retirement. This authority follows all our careers, they prepare and pay pensions, they also offer some specific following for vulnerable people and they have their own studies Department.
Foundation de France role is to collect and distribute funds for sponsorships projects. One of their major axis is to contribute for helping vulnerable people projects.

A first meeting of this ethical Committee will take place in April 2015. The first meeting objective is to discuss and to validate the experimentation process for users (elderly people).

During the project, this committee will be requested every time an ethical or sensible topic will appear.
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3.2 French Scientific and Ethics Committee rules

This Committee's mission is to support, to study and to approve developments considered or hired by ACCESS within the framework of the conception and of the deployment of its services package aimed at seniors and caregivers. Its works will ensure the respect of its products and services proposed in regards to personal freedoms, the private life of its users and the confidentiality of transmitted information.

Project: Rules of Procedure of the ACCESS Ethics Committee-
This document will have to be improved by the Committee partners.

Article 1:
This present document sets out the rules of operation of the ACCESS Scientific and Ethics Committee (CSE).

Article 2:
The CSE ensures the respect of personal freedoms, the respect of confidentiality of transmitted information, and more broadly, compliance services offered by ACCESS with good practices and operation of relevant providers. It will rely as appropriate on the services of CNIL (National Commission for Information Technology and Civil Liberties).

Article 3:
The CSE and its prerogatives will be integrated into the rules of procedure of the SAS or of any other legal entity in charge of the marketing of the services package with the Aide and Home Care structures or any other client.

Article 4:
This Committee includes project representatives, social action professionals, its funding
and its ethics, its customers and other competent authorities regarding Human Rights.
The members of this Committee may be proposed by the structure responsible to market the services package and then be elected by the CSE.
The CSE elects its president among its members.

Article 5:
The Committee is independent from the company or from any other structure in charge of the marketing of the services package.
The role of CSE members is voluntary and its members should not have any direct or indirect link, with the operation results of the said company.
As such, the company or any other structure responsible for the marketing of the services package, is prohibited any distribution of bonuses and other incentives of the results of the company to the members of the Committee.

Article 6:
Within the framework of the ACCESS project, the Committee is informed by the leader, of any new development, services, projects or stage of development.
In case of marketing and creation of a structure responsible thereof, this information will be provided in the rules of procedure of the said company.

Article 7:
The Committee may be requested, as part of its objectives and its missions, by the carrier of the project or which is responsible for marketing the services package, but also by any representative authority of the sector.
The Committee is requested directly and in writing. An acknowledgement of receipt shall be restored to the applicant. Depending on the application and on assessment of the President, he will appoint two reporters for the drafting of a notice on which the Committee will decide within a period of 6 weeks.

Article 8:
The Committee meets at least twice per year.
It can also meet at the request of its president or of at least half of its members.
Any summons is done on an agenda, agenda drawn up of the meeting concerned. The summons shall be sent to the members at least 25 working days before the relevant date. The convening is left to the discretion of the Committee (courier, mail or otherwise).
The Committee can also deliberate remotely in the same conditions via video conference.

Article 9:
The Committee cannot deliberate unless more than half of its members are present. The deliberations shall be adopted by a majority of the members present. In the absence of the President, a Chairperson will be appointed among the members present. In case of even number and equal vote, the voice of the President will be prominent.

Article 10:
The Committee's recommendations are forwarded to the leader, within the framework of the project, in the direction of the structure responsible for marketing the services package in the event of success, and, in copy, to the members of the Committee.

Article 11:
The Committee shall draw up minutes of the meeting which will be forwarded to the members present and validated during the following Committee.

Article 12:
The President will ensure the correct application of this regulation.

Article 13:
After deliberation, the tasks of this Committee may be expanded to other sites linked to ACCESS, associated in the care and support of seniors at home. On these bases, an association can be created.

4 Ethical Committee in Belgium

In Belgium are available ethical committee at national level. This means that each person can present questions one of the ethical committee. The partner FamilieHulp has identified one of the possible committee and has obtained its support for the ACCESS project.
The selected committee is:
ALGEMEEN ZIEKENHUIS GROENINGE
GEMEENTE – COMMUNE : **8500 KORTRIJK**
Contact emails :
ethisch.comite@azgroeninge.be;
peter.doubel@azgroeninge.be;
sofie.desmet@azgroeninge.be;
hanna.deman@azgroeninge.be;
kaat.verstaen@azgroeninge.be

A full list of available committee can be found in Appendix C: ” List of Belgian official ethical committee”.

4.1 About the Federal Agency for Medicines and Health Products in Belgium (FAMHP)

The FAMHP is the competent authority responsible for the quality, safety and efficacy of medicines and health products. It works together with health professionals and other competent authorities at the

national and international level to ensure the population the optimal use of the medicines and health products they need.
In the interest of public health the FAMHP ensures the quality, safety and efficacy of medicines and health products in clinical development and on the market.

Federal Agency for Medicines and Health Products (FAMHP) - (former Directorate-General for Medicinal Products of the FPS Public Health)
Created: 01.01.2007
Minister responsible (till 2014): Laurette Onkelinx, Vice-Prime Minister and Minister of Social Affairs and Public Health
Chief Executive Officer: Xavier De Cuyper
This Federal Angency is a **Public service institution with a legal personality, classified under category A** Competent authority for the quality, safety and efficacy of medicines and health products
Fields of competency: research and development (R&D), registration and marketing authorisation, production and distribution (inspection and control activities), vigilance, proper use of medicines and health products
Personnel: 390 employees on 01.01.2012 most with scientific qualifications (doctors, pharmacists, veterinarians)
Slogan : "Your medicines and health products are our concern."

4.2 About a clinical trial in Belgium

A clinical trial can only start after receiving a favorable opinion from Ethics Committee and if relevant authority (FAMHP : R&D) has not indicated any major insufficiency within the legal timeframe.

4.3 Legal texts

In Belgium the European directive 2001/20 has been incorporated in national law by the **law 7th May 2004** published in the Belgian Monitor of 18th May 2004. The new legal framework has been in force since 1st May 2004.

The law of 7 May 2004 has been modified several times (see below).

Note: the laws, royal decrees and circulars are (except for a few) not translated in English. Therefore we refer to the links on the French and the Dutch version of the website.

4.4 Link to laws

Law dated 7th May 2004 (French version) related to experiments on human people.

Modified by the following laws :

Programme law dated 27/12/04 (French version) modifying the law dated 7/05/04 (French version)

Programme law dated 27/12/05 (French version)

Health law dated 13th December 2006 (French version)

Programme law dated 13th December 2006 (French version)

Programme law dated 27th April 2007 (French version)

Law dated 24th July 2008 related to various dispositions (French version)

Law dated 19th December 2008 related to various health dispositions (French version)

4.5 Link to Royal Decrees (laws)

Royal Decree dated 22th April 2007 fixing the fees to be paid in the framework of article 30, § 6 of the law dated 7th May 2004 (French version) relating to experiments on human people.

Royal Decree dated 30th June 2004 (French version) determining the measures for carrying out the law dated 7th May 2004 (French version) relating to the experiments on human people concerning clinical trials of medicines for human use, modified by the

Royal Decree dated 18th May 2006 (French version)

Royal Decree dated 15th July 2004 (French version) determining the fees to be paid for a request for an opinion or for authorisation to conduct a clinical trial or an experiment.

4.6 Link to Circulars (operational instructions)

Circular 609 (PDF, 1.49 MB) (04/04/2014) (french version) : List of ethics committees having full approval according to the law dated 7th May 2004 related to experiments on human people.

Circular 607 (PDF, 2.37 MB) (french version) : Pending payments for ethics committees (2011)

Circular 604 (PDF, 595.05 Kb) (French version) : Template for informed consent. English version (PDF, 176.97 Kb).

Circular 597 (PDF, 849.18 Kb) (28/03/2013) (French version) : Pending payments for ethics committees (2010)

Circular 584 (PDF, 947.79 Kb) (14/02/2012) (French version) + annex (DOC, 204.5 Kb) : Pending payments for ethics committees (2009)

Circular 573 (PDF, 399.51 Kb) (French version) : Pending payments for ethics committees

Circular 566 (PDF, 152.96 Kb) (French version) : Pending payments for ethics committees (2007)

Circular 512 (PDF, 1.42 MB) (French version) : Pending payments for ethics commissions - Indexation of the amounts for experiments - Data for the interactive website - 2007 activity reports

4.7 Link to some 'Orientation documents'

Eudralex Volume 10

The following information is available for the ethics committees to do their tasks as laid down in the law on the experiments: Manual for non-interventional trials: this version is available in Dutch and French.

FAMHP has compiled an informed consent template to be used in Belgium. A copy of the template and its rules can be found in "APPENDIX F: Belgium Informed Consent". The form will have to be updated with the correct details of the ACCESS project, referent people and all necessary information to help subjects to make a correct informed decision.

5 Privacy

In research it is necessary and obligatory to take into account **privacy issues** and protect the personal data of the participants. In this sense, we can quote the *Article 8 of the European Charter of Fundamental Rights: "Everyone has the right to the protection of personal data concerning him or her"*. The data from the participants must be processed fairly for specified purposes in the project and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Every participant has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

The access to stored data will be available only to related partners in this task. The data stored will be used for the solely purpose of the objectives of the ACCESS project and it will be destroyed at the end of the project. In any case disclosing of data shall be done only safeguarding the anonymous and stored in aggregate.

The consortium shall ensure that the processing and movement of data fulfils the principles and requirements of national laws in each case, and above all, the principles of the *European Directive 95/46/EC* on the protections of individuals. Every partner shall follow the national law on this regard.
For each country involved, the following frameworks and authorities are involved:

Country	**Legal National Framework**
FRANCE	National Law no. 2004-801 of 6th August 2004
ITALY	Legislative Decree no. 196 of 30 June 2003
BELGIUM	Law 7th May 2004

6 Appendix A: “ACCESS: Regole Etiche in Italia”

Gli aspetti etici del progetto ACCESS riguardano:

- 1. la volontarietà/autodeterminazione di pazienti e care giver, formali e informali, alla partecipazione alla sperimentazione
- 2. la tutela della privacy nel trattamento dei dati personali, sensibili e sanitari delle persone coinvolte;
- 3. le misure di sicurezza degli archivi informatici, delle reti telematiche, delle connessioni wireless;
- 4. le regole da adottare per la predisposizione ed erogazione per via telematica di servizi sanitari e socio-sanitari;
- 5. la responsabilità medico-legale del personale sanitario/assistenziale coinvolto.

1. Volontarietà/autodeterminazione alla partecipazione alla sperimentazione

I partecipanti alla sperimentazione del progetto ACCESS, selezionati con sistema casuale nell’ambito dei pazienti in cura presso il Centro Regionali Alzheimer dell’Università di Roma Tor Vergata, saranno adeguatamente informati delle finalità, modalità di svolgimento e criteri di raccolta dei dati sensibili attuati durante la verifica sperimentale condotta tramite il Progetto ACCESS.
Ciascun partecipante e/o care giver, formale e informale, sottoscriverà un Consenso Informato, predisposto dai ricercatori del CAR, per il periodo di svolgimento della sperimentazione.
Ciascun partecipante e/o care giver, formale e informale, potrà in qualsiasi momento recedere dalla partecipazione al progetto ACCESS.

2. Tutela della privacy e protezione dei dati personali

In Italia la protezione dei dati personali è tutelata dal D.lgs. 30 giugno 2003 n° 196 “Codice in materia di protezione dei dati personali”. In accordo a questa legge, il trattamento dei dati si svolgerà nel rispetto dei diritti e delle libertà fondamentali delle persone coinvolte, nonché della loro dignità, con particolare riferimento alla riservatezza, all’identità personale e al diritto alla protezione dei dati personali.
Tutte le informazioni fornite dai partecipanti coinvolti nel progetto, che riguarderanno dati personali ritenuti “sensibili”, compresi i dati personali idonei a rivelare lo stato di salute, saranno utilizzate per operazioni pertinenti e strettamente necessarie al progetto; il nome dei partecipanti coinvolti non verrà divulgato e ogni persona sarà tutelata dalla massima riservatezza (art.7 Dlgs 196/2003) e non sarà possibile rintracciarla per scopi esterni al progetto.

3. Misure di sicurezza degli archivi informatici, delle reti telematiche, delle connessioni wireless

Il titolare dell’archiviazione e della trasmissione dei dati (azienda Liferesult) e il titolare del trattamento dei dati (Centro Regionale Alzheimer) saranno tenuti a informare dettagliatamente gli interessati sulle finalità e le modalità del trattamento cui sono destinati i dati, accertandosi che ne abbiano appreso il significato.

Le chiavi di accesso ai codici usate dai ricercatori locali non saranno condivise con ricercatori esterni o con altri che non prendano parte al progetto. Il nome delle persone coinvolte non sarà utilizzato in risultati che verranno pubblicati, se non dopo aver ottenuto il loro consenso, e tutti i dati personali saranno considerati confidenziali (art. 13 D.Lgs. 196/2003). Completata l’indagine, i dati saranno codificati in modo da non contenere identificazioni personali e saranno rintracciabili nel database solo tramite un codice.

Il titolare dell'archiviazione e della trasmissione dei dati dovrà prevedere adeguate forme di tutela per garantire la massima affidabilità e integrità dei dati trasmessi tramite supporto telematico.

4. Regole da adottare per la predisposizione ed erogazione per via telematica di informazioni e servizi sanitari e socio-sanitari

Il titolare dei trattamenti medici (Centro Regionale Alzheimer) detta le regole per la registrazione e l'archiviazione di dati anagrafici, sociali e sanitari, di bio-immagini e altri documenti medici del paziente necessari durante la sperimentazione ACCESS, in linea con le regole del SSN Italiano. Lo stesso stabilisce le modalità di attuazione dei servizi di teleassistenza e telemonitoraggio di alcuni parametri biometrici previsti dalla sperimentazione ACCESS.

5. Responsabilità medico-legale del personale sanitario/assistenziale coinvolto

La responsabilità medico-legale di ogni intervento sanitario/assistenziale verso il paziente e il care giver formale e informale coinvolto nel progetto ACCESS è del Centro Regionale Alzheimer.

Ogni intervento medico-sanitario svolto a distanza verso il paziente e il care-giver, formale e/o informale, sarà sottoposto ad un sistema di validazione dal personale sanitario responsabile, riconoscibile dal paziente e/o dal care giver.

7 Appendix B: “Règlement interieur comité éthique”

Comité Ethique & Scientifique

Ce comité a pour mission l’accompagnement, l’étude et l’agrément des développements envisagés ou engagés par ACCESS dans le cadre de la conception et du déploiement de son bouquet de services à destination des seniors et des aidants. Ses travaux s’assureront du respect des produits et services proposés au regard des libertés individuelles, de la vie privée des usagers et de la confidentialité des informations transmises.

Règlement Intérieur du Comité Ethique ACCESS

Article 1 :
Ce présent document fixe les règles de fonctionnement du Comité Scientifique & Ethique ACCESS (CSE).

Article 2 :
Le CSE s’assure du respect des libertés individuelles, du respect de la confidentialité des informations transmises et plus largement, de la conformité des services proposés par ACCESS avec les bonnes pratiques et le fonctionnement des prestataires concernés.

Article 3 :
Le CSEP et ses prérogatives seront intégrés au règlement intérieur de la SAS ou de toute autre entité juridique chargée de la commercialisation du bouquet de services auprès des Structures d’Aide et de Soin à Domicile ou de tout autre client.

Article 4 :
Ce comité comprend des professionnels de l’action sociale, de son financement et de son éthique, des clients et autres instances compétentes en matière de Droit de l’Homme.
Les membres de ce comité pourront être proposés par la structure chargée de commercialiser le bouquet de services puis élu par le CSEP.
Le CSEP élit son président parmi ses membres.
Il sera doté d’un secrétariat, d’une adresse postale, d’une boite aux lettres confidentielles et d’un budget de fonctionnement propre

Article 5 :
Le comité est indépendant de la société ou de toute autres structures chargée de la commercialisation du bouquet de Services.
La fonction de membre du CSEP est bénévole et ses membres ne doivent avoir aucun lien, direct ou indirect avec les résultats de l’exploitation de la dite société.
A ce titre, la société ou toute autre structure chargée de la commercialisation du bouquet de service, s’interdit toute distribution de primes et autres intéressements aux résultats de l’entreprise aux membres du comité.
Si dans son fonctionnement, il apparaît qu’un membre du Comité a un intérêt économique quelconque avec un produit ou service développés ou proposés par la dite structure, celui-ci devra porter connaissance de ce conflit d’intérêts aux membres du Comité et se récuser.

Article 6 :

Dans le cadre du projet Access, le comité est informé par le chef de file, de tout nouveau développement, services, projets ou étape de développement de ceux-ci.
En cas de commercialisation et de création d'une structure chargée de celle-ci, cette information sera prévue au règlement intérieur de la dite société.

Article 7 :
Le comité peut être saisi, dans le cadre de ses objectifs et de ses missions, par le porteur du projet ou la structure chargée de commercialiser le bouquet de services, mais aussi par toute instance représentative du secteur.
Le comité est saisi directement et par écrit. Un accusé de réception devra être remis au demandeur.
En fonction de la demande et sur appréciation du Président, celui-ci désignera deux rapporteurs chargés de la rédaction d'un avis, avis sur lequel statuera le Comité et ce, dans un délai de 6 semaines.

Article 8 :

Le comité se réunit au moins une fois par trimestre.
Il peut aussi se réunir à la demande de son président ou d'au moins la moitié de ses membres.
Toute convocation se fait sur un ordre du jour, ordre du jour arrêté lors de la réunion concerné. La convocation doit être adressée aux membres au moins 25 jours ouvrables avant la date concernée.
La convocation est laissée à l'appréciation du comité (courrier, mail ou autre).
Le comité peut également délibérer à distance dans les mêmes conditions via une visio conférence

Article 9 :
Le Comité ne peut délibérer que si plus de la moitié de ses membres sont présents. Les délibérations sont adoptées à la majorité des membres présents.
En cas d'absence du Président, un Président de séance sera nommé parmi les membres présents.
En cas de nombre pair et d'égalité lors du vote, la voix du Président sera prépondérante.

Article 10 :
Les recommandations du comité sont transmises au chef de file, dans le cadre du projet, à la direction de la structure chargée de commercialiser le bouquet de service en cas de réussite de celui-ci, et, en copie, aux membres du Comité.

Article 11 :
Le comité établit un procès verbal de la réunion qui sera transmis aux membres présents et validés lors du comité suivant.

Article 12 :
Le Président veillera à la bonne application du présent règlement.

Article 13
Après délibération, les missions de ce comité pourront être élargies, à d'autres chantiers qu'Access ayant un lien avec la prise en charge et l'accompagnement des seniors à domicile.
Sur ces bases, une association pourra être créée.

8 Appendix C: “List of Belgian official ethical committee”

ZIEKENHUIS - HOPITAL	GEMEENTE - COMMUNE	EMAIL
ZIEKENHUISNETWERK ANTWERPEN	2020 ANTWERPEN	ethische.commissie@zna.be; dedeyn@skynet.be
CLINIQUES UNIVERSITAIRES (U.C.L.) - MONT-GODINNE	5530 MONT-GODINNE	comite.ethique-montgodinne@uclouvain.be; patrick.evrard@uclouvain.be
ALGEMEEN ZIEKENHUIS ST.-JAN BRUGGE-OOSTENDE	8000 BRUGGE	stephanie.claeys@azbrugge.be; ludo.vanopdenbosch@azbrugge.be; ethisch.comite@azsintjan.be
CENTRE HOSPITALIER UNIV. ST.-PIERRE (BRUXELLES)	1000 BRUXELLES	comite_ethique@stpierre-bru.be; Annie_KERCKX@stpierre-bru.be; etienne_stevens@stpierre-bru.be
CENTRE HOSPITALIER UNIVERSITAIRE BRUGMANN	1020 LAEKEN	christine.potie@chu-brugmann.be; joseph.valsamis@chu-brugmann.be
INSTITUT JULES BORDET	1000 BRUXELLES	comite.ethique@bordet.be; thierry.gil@bordet.be
GZA- ZIEKENHUIZEN	2610 WILRIJK	bart.vandeneynden@gza.be; willeke.dijkhoffz@gza.be; hilde.maes@gza.be; liesbeth.terijdt@gza.be
H.- HARTZIEKENHUIS ROESELARE – MENEN	8800 ROESELARE	lharlet@hhr.be; sdeneve@hhr.be; bdebock@hhr.be
ONZE LIEVE VROUW ZIEKENHUIS AALST	9300 AALST	Antoon.Leloup@olvz-aalst.be; carla.hooft@olvz-aalst.be; nadine.de.neef@olvz-aalst.be
UNIVERSITAIR ZIEKENHUIS BRUSSEL	1090 JETTE	commissie.ethiek@uzbrussel.be; christel.vansteenkiste@uzbrussel.be
JESSAZIEKENHUIS	3500 HASSELT	ethische.toetsingscommissie@jessazh.be; koen.magerman@jessazh.be; katrien.jaemers@jessazh.be
ALGEMEEN ZIEKENHUIS ST. LUCAS GENT	9000 GENT	cme@azstlucas.be; han.martens@azstlucas.be
UNIVERSITAIR ZIEKENHUIS ANTWERPEN	2650 EDEGEM	ethisch.comite@uza.be; patrick.cras@ua.ac.be; patrick.cras@uza.be
UNIVERSITAIRE ZIEKENHUIZEN K.U.L.	3000 LEUVEN	ec@uzleuven.be; walter.vandenbogaert@uzleuven.be; margareta.verbeeck@uzleuven.be; sabine.graux@uzleuven.be
ZIEKENHUIS OOST – LIMBURG	3600 GENK	patrick.noyens@zol.be; ec.submission@zol.be
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CENTRE HOSPITALIER REGIONAL DE LA CITADELLE	4000 LIEGE	marie.louise.frenay@chrcitadelle.be; francois.damas@chrcitadelle.be

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CENTRE HOSPITALIER UNIVERSITAIRE DE LIEGE	4000 LIEGE-1 (SART-TILMAN)	ethique@chu.ulg.ac.be; v.seutin@ulg.ac.be; l.delattre@ulg.ac.be

9 APPENDIX D: Italian Informed Consent

"ACCESS: Consenso informato"

Gentile Signora/e,

Il CAR, Centro Regionale Alzheimer del Policlinico Università di Roma Tor Vergata invita Lei e/o i Suoi famigliari a partecipare al Progetto cofinanziato dall'UE nell'ambito del programma AAL-JP:
ACCESS, Assisting Carers for CooperativE Services to Seniors
ACCESS, Assistere i care givers nei servizi telematici di cura a domicilio degli anziani

Pratica MIUR - n. PROG. 280/281 2012 DM 593

Per prima cosa, vogliamo che Lei sappia che:
- il **D.lgs. 196/2003** prevede il diritto alla protezione dei dati personali. In conformità a questa legge, il trattamento dei dati che emergeranno dalla sperimentazione prevista dal Progetto si svolgerà nel rispetto dei diritti Suoi e dei Suoi famigliari e delle libertà fondamentali, nonché della Sua dignità, con particolare riferimento alla riservatezza, all'identità personale e al diritto alla protezione dei Suoi dati personali.

- La partecipazione Sua e dei Suoi famigliari a questo Progetto è **volontaria e a titolo completamente gratuito.** Lei può scegliere di non partecipare e può ritirarsi dalla partecipazione in qualunque momento, previa comunicazione al CAR.
- La Sua partecipazione a questo Progetto non comporta nessun onere aggiuntivo, oltre alla Sua disponibilità di tempo e a quella eventuale dei Suoi famigliari.
- Le attività e i contenuti previsti dal presente Progetto non sono sostitutivi di alcuna attività di prevenzione, diagnosi, cura e riabilitazione previste dal Suo piano di cura, ma affiancano le indicazioni terapeutiche definite dai Sanitari. Lei potrebbe anche non ricevere benefici diretti dalla partecipazione al Progetto. La Sua collaborazione può però fornire ai ricercatori elementi conoscitivi che potranno, nel prossimo futuro, aiutare altre persone, e probabilmente anche Lei.
- L'obiettivo di questo Progetto è elaborare un sistema di monitoraggio a distanza, attraverso una piattaforma informatica**,** realizzata dall'azienda partner di progetto LIferesult**,** sulla base di indirizzi messi a punto dal team di medici e ricercatori che partecipano al Progetto (coordinati dal prof. Giuseppe Sancesario, responsabile del CAR). Le informazioni che Lei e/o i Suoi famigliari sarete chiamati a fornire al CAR saranno trasmesse direttamente dalla Sua abitazione. Il gruppo medico del CAR le potrà visualizzare a distanza per verificare a cadenze predefinite l'andamento del Piano di cura e per fornire a Lei e/o ai Suoi famigliari adeguati elementi informativi in relazione ad aggiornamenti o eventuali modifiche delle prescrizioni terapeutiche stabilite.

La sperimentazione che La riguarda si effettuerà presso la Sua abitazione, nei tempi e nei modi che saranno concordati da Lei e/o i Suoi famigliari con il coordinatore di Progetto del CAR (prof. Giuseppe Sancesario).
Per attuare il programma sperimentale il CAR, in collaborazione con il partner informatico Liferesult, Le consegnerà a domicilio il seguente kit di elementi:

- un tablet con connessione internet
- un dispositivo da indossare per rilevare alcuni parametri vitali.

- Il tablet consentirà a Lei e/o ai Suoi famigliari di comunicare con il CAR, trasferire al personale medico che l'ha in cura informazioni, dati e documenti, secondo un'agenda che sarà definita di comune accordo con il CAR.
- Attraverso il tablet, chiederemo a Lei e/o ai Suoi famigliari di registrare eventuali situazioni o eventi critici indicati dal CAR.
- Sarà anche richiesto a Lei e/o ai Suoi famigliari di trasmettere a cadenze prestabilite i risultati di alcune analisi strumentali e di laboratorio, secondo quanto indicato dal CAR
- Il dispositivo da indossare, con il consenso Suo e/o dei Suoi famigliari, rileverà alcuni parametri vitali, utili per stabilire eventuali effetti critici delle terapie farmacologiche sulle Sue condizioni di salute.
- Tutti i dati rilevati, sia quelli trasmessi da Lei e/o dai Suoi famigliari, sia quelli rilevati automaticamente tramite il dispositivo indossabile, saranno inviati tramite internet ad un server remoto, e custoditi in apposito data base presso l'azienda Liferesult. Un software di elaborazione dati delle informazioni ricevute consentirà all'équipe medica del Car di valutare periodicamente i dati trasmessi.
- Tutte le apparecchiature installate presso la Sua abitazione per le finalità del presente Progetto saranno rimosse e restituite al CAR a conclusione della sperimentazione, per poter poi essere utilizzate da eventuali altri utenti.

- Le modalità di realizzazione della sperimentazione saranno precisate a Lei e ai Suoi famigliari in uno specifico documento, che le sarà consegnato al momento della Sua adesione al progetto.

Se Lei e/o i suoi famigliari deciderete di partecipare al Progetto ACCESS, Vi chiederemo inoltre di rispondere ad alcune domande relative alle Sue condizioni di salute e/o alle Sue aspettative, attraverso un'intervista iniziale ed una a conclusione della sperimentazione. Il questionario sarà somministrato a Lei e/o ai Suoi famigliari dai nostri operatori. In concreto, l'intervista, che durerà al massimo 50 minuti, chiederà a Lei e/o ai Suoi famigliari:

le Sue preferenze, attitudini e valutazioni riguardo alle Sue condizioni di salute e allo stile di vita Suo e/o dei Suoi famigliari; difficoltà, problemi o eventuali osservazioni rilevate nel corso della sperimentazione, nell'uso del tablet e nell'utilizzo del dispositivo indossabile; una valutazione conclusiva Sua e/o dei Suoi famigliari sui vantaggi/svantaggi del sistema **ACCESS.**

Le chiediamo inoltre il consenso Suo e/o dei Suoi famigliari ad essere ripreso/a con una telecamera durante la prova dei test e all'utilizzo di eventuali fotografie o riprese video rappresentative del test

in incontri/convegni/attività di studio, informazione e divulgazione delle modalità di funzionamento e utilizzo del Sistema ACCESS.

La partecipazione Sua e/o dei Suoi famigliari al Progetto consisterà nell'eseguire periodicamente (secondo il programma stabilito dal CAR) le attività che Le saranno proposte dall'équipe medica del CAR per complessive 2 settimane (o altro termine da definire con il CAR).

Per facilitare la fase di sperimentazione, il CAR proporrà a Lei e/o ai Suoi famigliari l'accompagnamento di un operatore del CAR e dell'azienda Liferesult, ai quali Lei e i Suoi famigliari potrete fare riferimento per qualsiasi necessità.

Compito degli operatori sarà anche quello di richiedere periodicamente a Lei e/o ai Suoi famigliari, o ogni volta che sarà necessario, alcune informazioni utili per valutare anche durante la sperimentazione l'efficacia del sistema e la presenza di eventuali difficoltà esecutive. Ciò consentirà ai ricercatori informatici di poter migliorare il sistema ACCESS adeguandolo alle esigenze degli utenti.

Qualora lo riterrà utile, in tutte le attività previste dal Progetto, potrà essere affiancato da un Suo famigliare o persona di fiducia da Lei indicata.

In calce al presente Modulo troverà tutti i numeri di telefono utili ai quali eventualmente segnalare problemi, disfunzioni, modifiche o per formulare eventuali domande rimaste insolute durante la sperimentazione o i colloqui con gli operatori.

Tutte le informazioni fornite da Lei e/o dai Suoi famigliari, che riguardano dati personali ritenuti "sensibili" per questo Progetto, saranno custodite presso l'azienda Liferesult, titolare del trattamento dei dati ai sensi dell'art. 13 del D.lgs. n. 196/2003, e utilizzate insieme alle informazioni ricevute dagli altri partecipanti, ma il Suo nome, né quello dei Suoi famigliari o altre persone da Lei indicate non verrà mai divulgato, la Sua persona e quella dei Suoi famigliari saranno tutelate dalla massima riservatezza (art.7 Dlgs 196/2003) e non sarà possibile rintracciarLe per scopi esterni al Progetto.

Completata l'indagine, tutti i dati sensibili saranno codificati in modo da non contenere identificazioni personali e saranno rintracciabili nel database solo tramite un numero.

Le chiavi di accesso ai codici usate dai ricercatori locali non saranno condivise con ricercatori esterni o con altri che non prendano parte al Progetto di ricerca. Il Suo nome o foto Sue o dei Suoi famigliari potranno essere eventualmente utilizzati solo dopo aver ottenuto il consenso Suo o dei Suoi famigliari, e tutti i Suoi dati personali saranno considerati confidenziali (art. 13 DLgs 196/2003).

I Suoi dati saranno utilizzati solo per questo studio e non saranno conservati per ricerche future. In conformità con la legge italiana sulla privacy D.Lgs 196/2003, il CAR e l'azienda Liferesult La informeranno che i Suoi dati saranno trattati con il massimo livello di riservatezza.

Questo Progetto è stato approvato da tutti i partner europei, dal MIUR e dal Comitato Etico del CAR per assicurare che sia conforme ai principi di conduzione di una ricerca che coinvolge persone fisiche.

Il/la sottoscritto/a …….

Dichiara di aver letto il presente documento informativo fornitomi dal CAR per conto del titolare del trattamento dei dati coordinatore Liferesult, ai sensi dell'art. 13 del D.lgs. n. 196/2003 sulle finalità e le modalità del trattamento cui sono destinati i dati, e di essere consapevole, in particolare, che il trattamento riguarderà dati "sensibili" di cui ha appreso il significato (art.4 comma 1 lett. d e art.26 D.lgs. 196/2003), e che potrebbero riguardare, tra l'altro, *" dati personali idonei a rivelare lo stato di salute"*:
Dichiara di aver avuto l'opportunità di discuterlo, e di aver potuto fare domande.

Il/La sottoscritto/a CONSENTE pertanto a partecipare al Progetto ACCESS, secondo le modalità che saranno concordate con gli operatori del CAR.

Il/La sottoscritto/a CONSENTE ad essere ripreso/a con una telecamera durante la prova dei test e all'utilizzo di eventuali fotografie o riprese video rappresentative del test in incontri/convegni/attività di studio, informazione e divulgazione delle modalità di funzionamento e utilizzo del Sistema ACCESS.

Il/la sottoscritt/oa inoltre CONSENTE che siano utilizzate, solo nell'ambito degli stessi operatori del progetto ACCESS ed esclusivamente per le finalità dello stesso Progetto, eventuali comunicazioni relative al proprio stato di salute o eventuale documentazione sanitaria che riguardi la propria persona.

FIRMA leggibile dell'interessato/a

……

FIRMA leggibile del/dei Famigliare/i

……

Numeri telefonici e recapiti utili:

CAR:

……

LIFERESULT:

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10 APPENDIX E: French Informed Consent

AUTORISATION
DE COMMUNIQUER
DES RENSEIGNEMENTS
CONTENUS DANS LE DOSSIER
MEDICAL

N° de dossier :
Date d'admission :

Nom et prénoms à la naissance :
Nom actuellement usité :
Adresse actuelle de l'usager :
N° de Sécurité sociale :
Date et lieu de naissance :

Je soussigné(e) :

Nom et adresse

En ma qualité de :

Usager ou personne autorisée

Autorise :

Nom prénom et adresse

A consulter les données contenues dans le dossier médical ci-dessus identifié :

Cette autorisation est valable pour une période de _____ jours à compter de la date de la signature de ce document.

Signataire : usager ou personne autorisée **Date :**

NB : les signataires de ce formulaire sont autorisés à le faire, conformément aux textes législatifs en vigueur. Le cas échéant, prière de mentionner à quel titre (curateur ou titulaire de l'autorité parentale) la personne est autorisée à signer.

AUTORISATION DE COMMUNIQUER DES RENSEIGNEMENTS CONTENUS DANS LE DOSSIER MEDICAL

11 APPENDIX F: Belgium Informed consent

Instructions for the proper use of the model Informed Consent Form

Format of the ICF[1]

The Ethics Committees opt for a format for the informed consent form in 3 parts:

1. the **information** essential to the decision to take part:
   This part must contain all the information essential to the decision-making process of the participant, such as
   a. a brief, clear presentation of the rights of the participant (voluntary participation; confidentiality; insurance, etc.)
   b. a clear description of the research project (context, objectives, methodology & course).
   c. descriptions of the risks & benefits.
2. **consent**;
3. **supplementary information** (appendices) that gathers together information that does not fall directly within the decision-making process but which includes
   a. useful information such as the number, frequency and content of each of the visits scheduled in the methodology,
   b. more detailed information on participants' rights

Editorial aspects

The ICF must be worded such that it can be read and understood by people who are not health-care professionals, who have not received verbal information and which potential participants may wish to consult (family, spouse, etc.).

The ICF must be written in a **language that is clear and understandable** for the participant:

a. **Structured** information, clear thread;
b. Correct sentence structure (attention to problems of literal translation from English to French/Dutch, inappropriate choice of terms, etc.);
c. Short sentences, language understandable for most of the participants at whom the document is directed.
d. No professional jargon;
e. Use the same terminology throughout the document for the same concept (example: do not refer to study then research then clinical trial).
f. Avoid the over-use of abbreviations.
g. No spelling mistakes;
h. Sufficiently large font size (reference: ≥ Arial 10), especially when the probable reader of the ICF is likely to have sight problems.

Administrative requirements

1. The 3 parts of the document, namely the information for the participant/legal representative, the consent and the appendices form a single document and are therefore identified by the same version number and the same date of issue.

[1] In the template, the text in red refers to instructions, draw attention to alternatives or propose a comment to the author of the document. The text in black suggests wordings we would like to see in the finalised ICF. The blue text indicates what must be addressed.

2. Each part will include the full title of the study in the original language of the document.
3. The pagination of the whole document will be presented in the format “page X/Y”.

Specific site adaptation: Replace the sequence information – consent – appendices by information – appendices – consent.

Title of the study: Official title in English and simplified version understandable for participants Sponsor of the study: *Name and address of the enterprise, hospital, university or other organisation; Name and address of CRO* Medical Ethics Committee: *Identification of the Ethics Committee that issued the single opinion on the trial and the local Ethics Committee that took part in the approval process.* Local investigators: *Name, affiliation and contact details*

Information vital to your decision to take part

Introduction

You are being invited to take part in an observational clinical study. This means that the treatment you have been offered was prescribed in the usual manner, in accordance with the conditions of good medical practice and independently of your possible participation in this study.
We are simply asking you whether we can collect data from your medical records to be able to combine them with those of other patients receiving the same treatment and to process them statistically for research purposes.
No additional diagnostic or monitoring procedure will be proposed.

[Or] Apart from a few questionnaires we will ask you to complete, no additional diagnostic or monitoring procedure will be proposed.

Before you agree to take part in this study, we invite you to take note of its implications in terms of organisation, possible risks and benefits, to allow you to make a decision with full awareness of the implications. This is known as giving “informed consent”.

Please read these few pages of information carefully and ask any questions you want to the investigator or his/her representative.

There are 3 parts to this document: the information essential to your decision, your written consent and supplementary information (appendices) detailing certain aspects of the basic information.

If you take part in this study, you should be aware that:

- The treatment offered to you by the investigator in accordance with current recommendations will not be altered if you take part in the study.
- This clinical study is being conducted after having been reviewed by one or more ethics committees.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, you can stop taking part by informing the investigator.

- The data collected on this occasion are confidential and your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You may contact the investigator or a member of his/her team at any time should you need any additional information.

Further information about your "Rights as a participant in a clinical study" can be found in appendix XX.

Objectives and course of the study

This clinical study has been organised to ….description of objectives in a few lines.

We are inviting you to take part in this clinical study because your doctor has offered you (describe the treatment) within the context of your clinical situation.

This clinical study is to include (number) patients, including approximately (number) in Belgium.

To be able to take part in this study you must …describe the inclusion/exclusion criteria for participants.

Your participation in the study will last the length of a single consultation, during which your doctor will ask you questions to gather all the data and information required for the study, such as your demographic data (age, weight, height, gender) as well as data concerning your medical history, your medication use, your diet, your addictions (smoking habits, alcohol consumption) … etc. (to be developed depending on the studies).

[Or] Your participation in the study will last around x months/years, during which, at each consultation visit proposed by your doctor, we will ask your doctor to send us information related to your treatment, to the progression of your clinical situation and your symptoms and the results of the prescribed examinations (specify … medical imaging examinations, biological examination, etc.).

[Depending on the studies] Your doctor will also ask you to complete several questionnaires to assess … (specify: your quality of life, your level of anxiety, etc…avoid using names of questionnaires that do not tell the patient anything)

Completing these questionnaires will take you x minutes during each consultation/during one of the annual consultations (specify)

Description of risks and benefits

As indicated above, neither the treatment that has been proposed nor the diagnostic and monitoring procedures for your clinical situation go beyond good medical practice. No risk, in terms of health, can be linked to your participation in this study.

Similarly, you should not expect any personal benefits as a result of taking part in the study. Know only that your participation will allow us to better understand … specify and thus to offer better treatments in the future.

Withdrawal of consent

Your participation is voluntary and you are entitled to withdraw your consent to take part in the study for any reason, without having to justify your decision.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

[If applicable] The sponsor/party responsible for the study may also decide to stop the study because the data collected provide a faster response than originally expected.

If you take part in this study, we ask you:

- To cooperate fully in the smooth running of this study.
- Not to conceal anything such as information relating to your state of health, the medication you are taking or the symptoms you are experiencing.
- To inform your doctor if you are asked to take part in another study to discuss with him/her the possibility of taking part in this study and to see whether you should then stop taking part in the present study.
- etc… such as the possible need for investigator/GP contact for the gathering of additional information when appropriate

Contact

If you need further information, but also if you have problems or concerns, you can contact the investigator (Surname, First name) or a member of his/her research team (Surname, First name) on the following telephone number

If you have any questions relating to your rights as a participant in a clinical study, you can contact the patient rights ombudsman[2] of your institution on this telephone number: telephone details. If necessary, he/she can put you in contact with the ethics committee.

[2] For trialsinvolving patients recruited outside of a hospital environment (trials in medical practices, non-hospital phase 1 research units), there is no reason to contact the patient rights ombudsman … in this case mention that the ethics committee may be contacted.