AXO-SUIT: Assistive exoskeleton suitable for elderly persons

AXO-SUIT DELIVERABLE

Work Package WP1:
End Users

Deliverable 1.2:
Ethical Procedure of Testing and Validation (Part 1)

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Ambient Assisted Living Joint Programme: National Funding Agencies for AXO-SUIT

Ambient Assisted Living Joint Programme

AXO-SUIT: Assistive exoskeleton suitable for elderly persons

Work Package Leader: **University of Limerick**
Work Package Members: Aalborg University
University of Gävle
University of Limerick
Welldana A/S
Bioservo Technologies AB
MTD Precision Engineering Ltd
Hjälpmedelsteknik Sverige
COMmeto bvba

AXO-SUIT Partnership:

Participant no.	Participant organisation name	Participant short name	Organisation type	Country
1 (Coordinator)	Aalborg University	AAU	Univ, End user	Denmark
2	University of Gävle	UGAV	Univ, End user	Sweden
3	University of Limerick	UoL	Univ, End user	Ireland
4	Welldana A/S	WELL	End user, IND	Denmark
5	Bioservo Technologies AB	BIOT	IND, business	Sweden
6	MTD Precision Engineering Ltd	MTD	IND, business	Ireland
7	Hjälpmedelsteknik Sverige	HJALP	End user	Sweden
8	COMmeto bvba	COM	IND, Business	Belgium

Ambient Assisted Living Joint Programme: National Funding Agencies for AXO-SUIT

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1. Executive summary

Background

AXO-SUIT will incorporate end user involvement across four European countries: Belgium, Denmark, Ireland and Sweden. Since end users will be closely involved in the design, development, testing and validation of AXO-SUIT, ethical issues surrounding the involvement of human participants in research must be considered. As specified within the Active and Assisted Living Programme, these ethical considerations will include issues surrounding informed consent; preservation of dignity, autonomy and values of end users; data protection, privacy and confidentiality; "exit strategies" for end users, and ethical dimensions of the AXO-SUIT solution itself.

Our Goals

- To formulate and adopt ethical procedures in the engagement of end users throughout the AXO-SUIT project

Our Approach and Course of Action

- Identify relevant ethics procedures in all AXO-SUIT partner countries that will apply to end users in the project, both for non-physical and physical involvement
- As Part 1 of a two-part deliverable, this document will describe the processes involved in obtaining approval from all relevant ethics authorities for all research involving end users which has been conducted to date
- This documents will also outline the preparations being undertaken to ensure that further research involving AXO-SUIT end users will be ethically sound

Our Findings and Results

- Each country within the AXO-SUIT consortium possesses its own individual regulations in relation to research ethics, reviewed and enforced by separate authorities
- Approval was successfully obtained for all research involving AXO-SUIT end users to date
- The application processes and timelines for obtaining ethics approval also vary greatly between countries, and must be considered when planning further end user consultation, testing and validation to prevent delays

Impact of the Deliverable

Ethical procedures have been adopted in the engagement of end users in the AXO-SUIT project to date, for both non-physical (Questionnaire 1 on end user functional requirements) and physical (study of human biomechanics during activities of daily living) involvement.

Planned Dissemination and Exploitation

As this is Part 1 of a two-part deliverable, the information contained in this document will inform future ethical considerations throughout the remainder of the AXO-SUIT project. For example, it was noted in this document that the timeline for obtaining approval can vary greatly between countries and the processes can be time-consuming, therefore documentation is already being prepared for future studies involving end users to minimise potential delays in receiving end user feedback on AXO-SUIT designs, and in testing and validation.

2. Introduction

The AXO-SUIT project aims to incorporate a strong focus on user-centred design, in order to ensure a successful system is developed [1]. As such, the project will involve primary and secondary end user volunteers, primarily from Belgium, Denmark, Ireland and Sweden, for whom personal data (such as mobility and handling capabilities, tasks performed in daily life requiring assistance, feelings about personal care robots and robot autonomy, interpretation of safety in presence of personal care robots, etc.), and opinions (referring to the impact on their life if the mobility and handling concepts in AXO-SUIT are fully or partially realised) will be collected. The involvement of human participants and the collection of sensitive data about health and behaviours mean that a number of ethical issues will be encountered.

An open and transparent procedure for formulating and finalising the ethical procedures to be adopted in the AXO-SUIT project will be implemented as part of Work Package 1 (WP1). Formal ethical approval will be applied for specifying the details of any research procedures to be carried out. National specific issues for local implementation will be formulated by the respective target country leaders, namely AAU for Denmark, UGAV for Sweden, UoL for Ireland and COM for Belgium. This will be a unified, cohesive process between partners to allow EU level testing of the project results.

Within the AAL Programme, specific ethical issues are defined that must be addressed, including [2]:

- Informed consent
- Preservation of the dignity, autonomy and values (human and professional) of end users
- Data protection, privacy and confidentiality (particularly in relation to sensitive data)
- "Exit strategies" for end users, both during the project's implementation and after its end
- Ethical dimensions of the solution itself e.g. distributive ethics, sustainability etc.

The engagement of end users in the AXO-SUIT project will be guided by these specific ethical issues, and appropriate consideration will be given to each.

Full informed, valid, written, signed consent will be obtained from all end user persons prior to their involvement in assisting with formulating the AXO-SUIT exoskeleton requirements, design concepts and commercialisation models, etc. Information sheets will be written in simple, non-technical terms so as to be easily understood by lay persons, and will include clear explanations of what is expected of participants, their roles, and the duration of their participation. Full contact details of the research staff responsible will be given in order to provide additional information if requested.

End users' dignity and autonomy will be preserved by considering potential vulnerabilities of participants and minimising any potential risks, discomfort or embarrassment in the research procedures adopted. End user participation will be on a strictly voluntary basis, and appropriate exit strategies for participants will be put in place.

Data protection and privacy issues will be addressed by ensuring that participant names and any other identifying information will not be available to any person or group other than the AXO-SUIT staff involved in the data gathering or those who have direct contact to the participant, and will not appear in any presentation or publication resulting from the AXO-SUIT work plan.

Confidentiality and security of sensitive patient data will be preserved, according to Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the protection of individuals with regard to the processing of personal data, and on the free movement of such data and to any relevant national regulations. All personal data, information or other variables associated with end users will be kept in secure computer files. The structure of the AXO-SUIT database will be such that the anonymity of the individual is preserved through the use of standardised number-letter code identifiers, as described in D1.1.

The personal aspects of the data collected in this project will not be used in a commercial way except to

generically specify the mobility and handling requirements for the AXO-SUIT aids to be developed within the project; nor will it be sold or made available to any third parties that could use it commercially.

In terms of exit strategies, participants will be free to end their involvement in the project at any stage without providing reasons. Participants will be given the opportunity to receive follow up information regularly after the project has ended, which will include details of when the products will be commercially available, and possibly offered reduced rates on purchases.

These general principles will guide strategies for end user engagement throughout the AXO-SUIT project. This document will describe in detail the ethical considerations and procedures necessary for the purposes of achieving safe, ethically sound end user engagement in specific aspects of the AXO-SUIT project. Details of processes already undertaken in each country will be provided, as will plans for future end user involvement throughout the user-centred design process.

3. Vocabulary and abbreviations

Term	Explanation
AAL	Active and Assisted Living
ADLs	Activities of Daily Living
DDPA	Danish Data Protection Agency
ECRN	Ethics Committee for Region Nordjylland
EUG	End User Group
FB	Full Body: test-rig or exoskeleton containing all components: LB, UB and TB.
LB	Lower Body: part of the test-rig or exoskeleton containing the legs.
Primary End User	The person who actually uses an AAL product or service, a single individual, "the well-being person". This group directly benefits from AAL by increased quality of life.
S&E REC	University of Limerick Science and Engineering Research Ethics Committee
Secondary End User	Persons or organisations directly being in contact with a primary end-user, such as formal and informal care persons, family members, friends, neighbours, care organisations and their representatives. This group benefits from AAL directly when using AAL products and services (at a primary end user's home or remote) and indirectly when the care needs of primary end-users are reduced.
Tertiary End User	Institutions and private or public organisations that are not directly in contact with AAL products and services, but who somehow contribute in organising, paying or enabling them. This group includes the public sector service organisers, social security systems, insurance companies. Common to these is that their benefit from AAL comes from increased efficiency and effectiveness which result in saving expenses or by not having to increase expenses in the mid and long term.
UB	Upper Body: part of the test-rig or exoskeleton: containing the arms and, in some setups, the glove.
WP	Work Package

4. Ethics Processes for End User Involvement – Non-Physical

AXO-SUIT will incorporate end user involvement across four European countries: Belgium, Denmark, Ireland and Sweden. Each country possesses its own individual regulations in relation to research ethics, reviewed and enforced by separate authorities.

This section will briefly describe the relevant research ethics processes followed to date in each country for end user involvement which does not include physical participation and testing with users, i.e. only users' opinions etc. are explored via methods such as questionnaires, interviews, and focus groups. At present, this non-physical testing primarily relates to Questionnaire 1 on end user functional requirements (full description in D1.3).

The following subsections will describe participant recruitment strategies and consent procedures, as well as data collection and protection procedures in each country of the AXO-SUIT consortium. Proof of ethics approval will also be included where applicable.

4.1. Belgium

4.1.1. Participants

In Belgium, primary end users are older adults (over 60 years of age) living at the service residences Melitza in Gent and Brugge. The study will be managed and executed by the team of the department of Neurology of the University Hospital Ghent. They have a longstanding experience in user-related questionnaires and are also taking care of the ethics committee approval process.

The research ethics are governed by the ethics committee of the University Hospital Ghent .The committee is primarily concerned with research related policies, procedures and governance. All departments of the University Hospital are required to plan and conduct their investigations in accordance with appropriate ethical standards. The University Hospital ethical committee considers the ethics of proposed research projects which will involve human subjects and to agree or not as to whether the projected research is ethical. This is according the Belgian laws and regulations with regard to any research involving human subjects or animal experimentations.

All research concerning AXO-SUIT involving human subjects, be it questionnaires or trials with end users, approval must be granted by the ethical committee. For the end user Questionnaire 1 approval is currently pending. A copy of the application form is included in Appendix F. The procedure for approval for human trials of AXO-SUIT, including physical end user involvement, is being started by the team.

4.1.1. Recruitment Procedure

As stated previously, primary end users are being recruited from those older adults (over 60 years of age) living at the service residences Melitza in Gent and Brugge. The selection of the people participating is on a voluntary basis. Currently a total of 40 people have expressed interest in participation and are ready to answer the questionnaire. The study will be managed and executed by the team of the department of Neurology of the University Hospital Ghent.

An information session will be held at the two Melitza locations for the people involved in the study after which the people will be asked to complete the questionnaire autonomously. The people participating in the study will also be asked if they are willing to participate in further studies, questionnaires and trials. This will ensure us an end user group ready for participation in end user testing of the AXO-SUIT solution.

4.1.2. Data Storage and Confidentiality

The study is performed under the governance of the department of Neurology of the University Hospital Ghent. All information will be anonymised, password protected and electronically stored at the University Hospital Ghent who is governing the study. The anonymised data will be made available to the AXO-SUIT team for further processing.

4.1.3. Approval from Research Ethics Committee

Approval is currently pending, but expected by mid February 2016.

4.2. Denmark

In Denmark, AAU is responsible for the involvement of end users, including seeking approval from the relevant ethics committees. Data protection and privacy issues for both Level 1 and Level 2 activities are governed by the Danish Data Protection Agency (DDPA) via a working committee at Aalborg University, while ethical issues related with experimental testing are governed by the Ethics Committee for Region Nordjylland (ECRN).

DDPA has granted permission to gather and store data concerning personal health condition throughout the entire project period (application included in Appendix A).

The application for ECRN on the experimental testing is underway.

4.2.1. Participants

In Denmark, primary end users are healthy elderly people over 60 years of age that primarily live in the area around Esbjerg and Aalborg.

4.2.2. Recruitment Procedure

Potential participants are be sourced via the AXO-SUIT project webpage (www.axo-suit.eu) or the network of WELL. In either case, the potential end users receive a formal invitation to join the AXO-SUIT project. For further interest, the end users receive a consent form, where the participant can assign their desired level of involvement in the project. Level 1 is the low-level of involvement and includes completion of questionnaires. Level 2 is the mid-level of involvement, and includes more in-depth reporting via e-discussions and meetings etc. in addition to Level 1 activities. Finally, Level 3 is the highest-level involvement, where the end users attend actual project events and have detailed and intensive involvement in the project.

4.2.3. Data Storage and Confidentiality

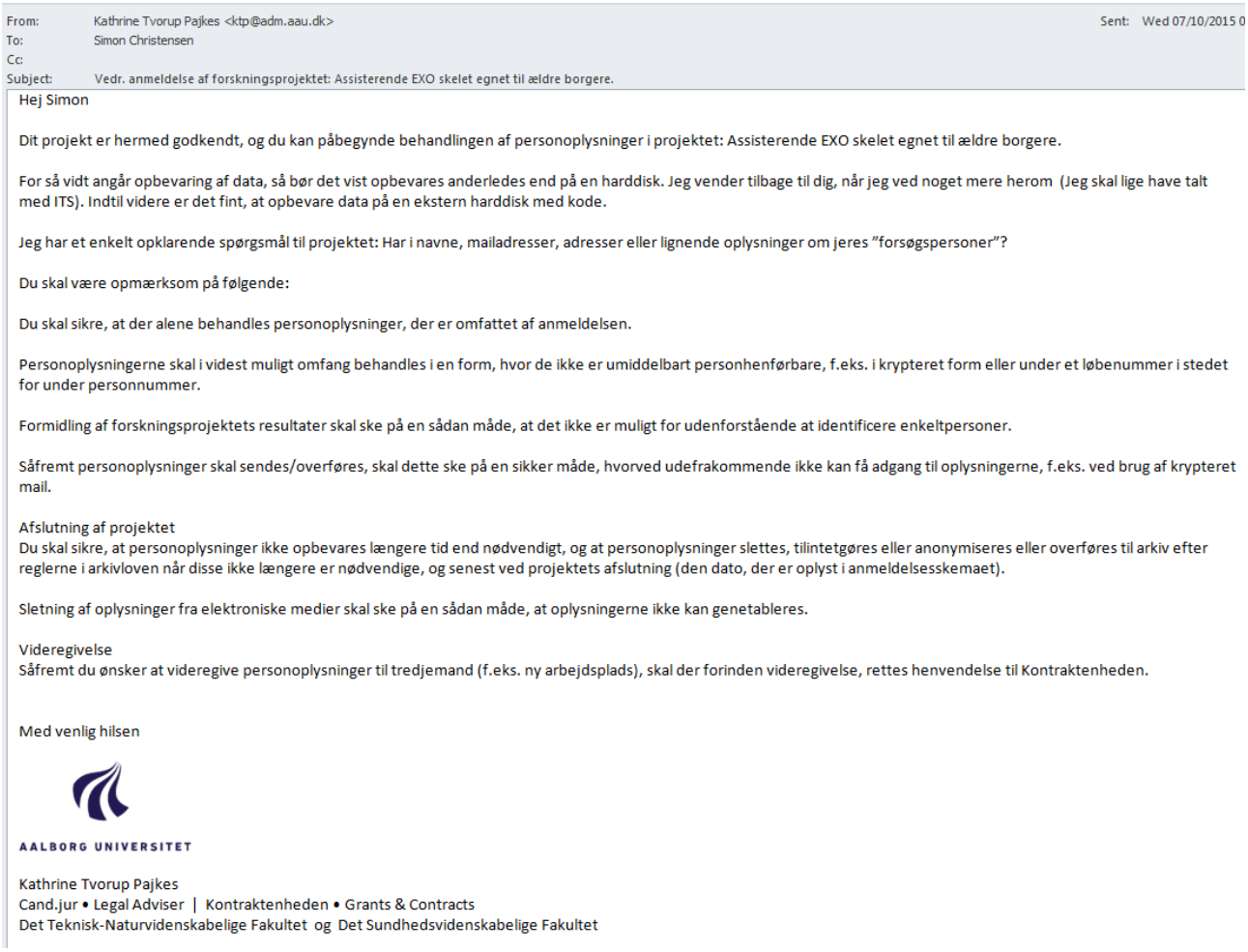
All questionnaires were completed anonymously. No information relating to a participant's identity is linked to the completed questionnaires. The hard copies of all completed questionnaires are scanned and stored electronically in password-protected files on external hard drives only accessible for AXO-SUIT researchers. The hard copies are subsequently shredded. Questionnaire results were coded, according to the format described in D1.1, but no information linking this code to any individual participant was retained.

Consent forms, including those containing contact details of participants and their level of involvement, are also being stored electronically in password-protected files. Only AXO-SUIT researchers have custody and access to the data collected. All data will be kept strictly anonymous for dissemination purposes.

In line with DDPA policy, electronic data will be deleted from the hard drive on which it is stored after 5 years.

4.2.4. Approval from Research Ethics Committee

A notification of approval for the data protection and privacy issues was received 07-10-2015 via e-mail (Figure 1). Confirmation of this approval was subsequently received from Aalborg University (Appendix B).



From: Kathrine Tvorup Pajkes <ktp@adm.aau.dk> Sent: Wed 07/10/2015 0
To: Simon Christensen
Cc:
Subject: Vedr. anmeldelse af forskningsprojektet: Assisterende EXO skelet egnet til ældre borgere.

Hej Simon

Dit projekt er hermed godkendt, og du kan påbegynde behandlingen af personoplysninger i projektet: Assisterende EXO skelet egnet til ældre borgere.

For så vidt angår opbevaring af data, så bør det vist opbevares anderledes end på en harddisk. Jeg vender tilbage til dig, når jeg ved noget mere herom (Jeg skal lige have talt med ITS). Indtil videre er det fint, at opbevare data på en ekstern harddisk med kode.

Jeg har et enkelt opklarende spørgsmål til projektet: Har i navne, mailadresser, adresser eller lignende oplysninger om jeres "forsøgspersoner"?

Du skal være opmærksom på følgende:

Du skal sikre, at der alene behandles personoplysninger, der er omfattet af anmeldelsen.

Personoplysningerne skal i videst muligt omfang behandles i en form, hvor de ikke er umiddelbart personhenførbare, f.eks. i krypteret form eller under et løbenummer i stedet for under personnummer.

Formidling af forskningsprojektets resultater skal ske på en sådan måde, at det ikke er muligt for udenforstående at identificere enkeltpersoner.

Såfremt personoplysninger skal sendes/overføres, skal dette ske på en sikker måde, hvorved udefrakommende ikke kan få adgang til oplysningerne, f.eks. ved brug af krypteret mail.

Afslutning af projektet
Du skal sikre, at personoplysninger ikke opbevares længere tid end nødvendigt, og at personoplysninger slettes, tilintetgøres eller anonymiseres eller overføres til arkiv efter reglerne i arkivloven når disse ikke længere er nødvendige, og senest ved projektets afslutning (den dato, der er oplyst i anmeldelsesskemaet).

Sletning af oplysninger fra elektroniske medier skal ske på en sådan måde, at oplysningerne ikke kan genetableres.

Videregivelse
Såfremt du ønsker at videregive personoplysninger til tredjemand (f.eks. ny arbejdsplads), skal der forinden videregivelse, rettes henvendelse til Kontraktenheden.

Med venlig hilsen

AALBORG UNIVERSITET

Kathrine Tvorup Pajkes
Cand.jur • Legal Adviser | Kontraktenheden • Grants & Contracts
Det Teknisk-Naturvidenskabelige Fakultet og Det Sundhedsvidenskabelige Fakultet

Figure 1. Email confirmation of approval from the DDPA to gather and store data concerning personal health during the AXO-SUIT project.

4.3. Ireland

In Ireland, UoL was responsible for the implementation of end user Questionnaire 1, including seeking approval from the relevant University ethics committee.

Research ethics policy at UoL is governed via the University of Limerick Research Ethics Governance committee. This committee is primarily concerned with research related policies, procedures and governance, whilst all research ethics applications are considered at Faculty level by Research Ethics Committees. All members of the University staff and students are required to plan and conduct their investigations in accordance with appropriate ethical standards. Faculty Research Ethics Committees are charged by the University to consider the ethics of proposed research projects which will involve human subjects and to agree or not as to whether the projected research is ethical.
Faculty Research Ethics Committees must be consulted about any research proposals which involve:

- Direct experimentation on individuals;
- Surveys or questionnaires administered to individuals;
- Use of data derived from individual records where individuals might be identified.
- Experimentation which involves animals.

For all research related to end users undertaken during the AXO-SUIT project, approval must be obtained from the Faculty of Science and Engineering Research Ethics Committee (S&E REC) before any research begins. A full ethics application must be made for any research involving adults aged 65 years and over (as is the case for Questionnaire 1), whereas an expedited application process is possible for research involving healthy adults aged 18-65 years. All S&E REC applications consider the following:

- Ethical dilemmas likely to be encountered in the research (such as informed consent, confidentiality and anonymity of participants, expertise of the researcher, protecting the rights of those involved) and indicate how they will be surmounted;
- Safety issues likely to be encountered by the researchers in the course of their fieldwork;
- The project's data storage needs.

4.3.1. Participants

Participants in Questionnaire 1 were adults aged 55 years and over, as these individuals represent the anticipated primary end users of AXO-SUIT. Participants in Ireland were English-speaking only, since translation resources were not available in Ireland.
Exclusion criteria were:

- Cognitive impairment, as this may limit the individual's capacity to provide informed consent to participate and/or to complete the written questionnaire, and
- Severe vision and hearing impairments – Information about the study and the questionnaire itself were provided in written format and/or verbally, thus it was necessary to exclude individuals who could not access information in these formats.

4.3.2. Recruitment Procedure

Potential participants will be sourced via local community groups/social clubs for older adults in Limerick City and County, North Tipperary and East Clare. Publicly available contact details will be used to contact the organisers of such groups. The group organisers will be invited by the researchers:

a) To notify their members of the opportunity to participate in this study, or
b) To have a member of the research team attend a group meeting to provide a brief 5-10 minute introduction and invitation to participate, or
c) To decline participation should the organiser deem the study to be inconvenient or inappropriate for their members.

Should options a) or b) be selected, contact details for the research team were provided to the group's members, and any individuals who wish to participate could contact the researchers to express their interest in participation.

4.3.3. Data Storage and Confidentiality

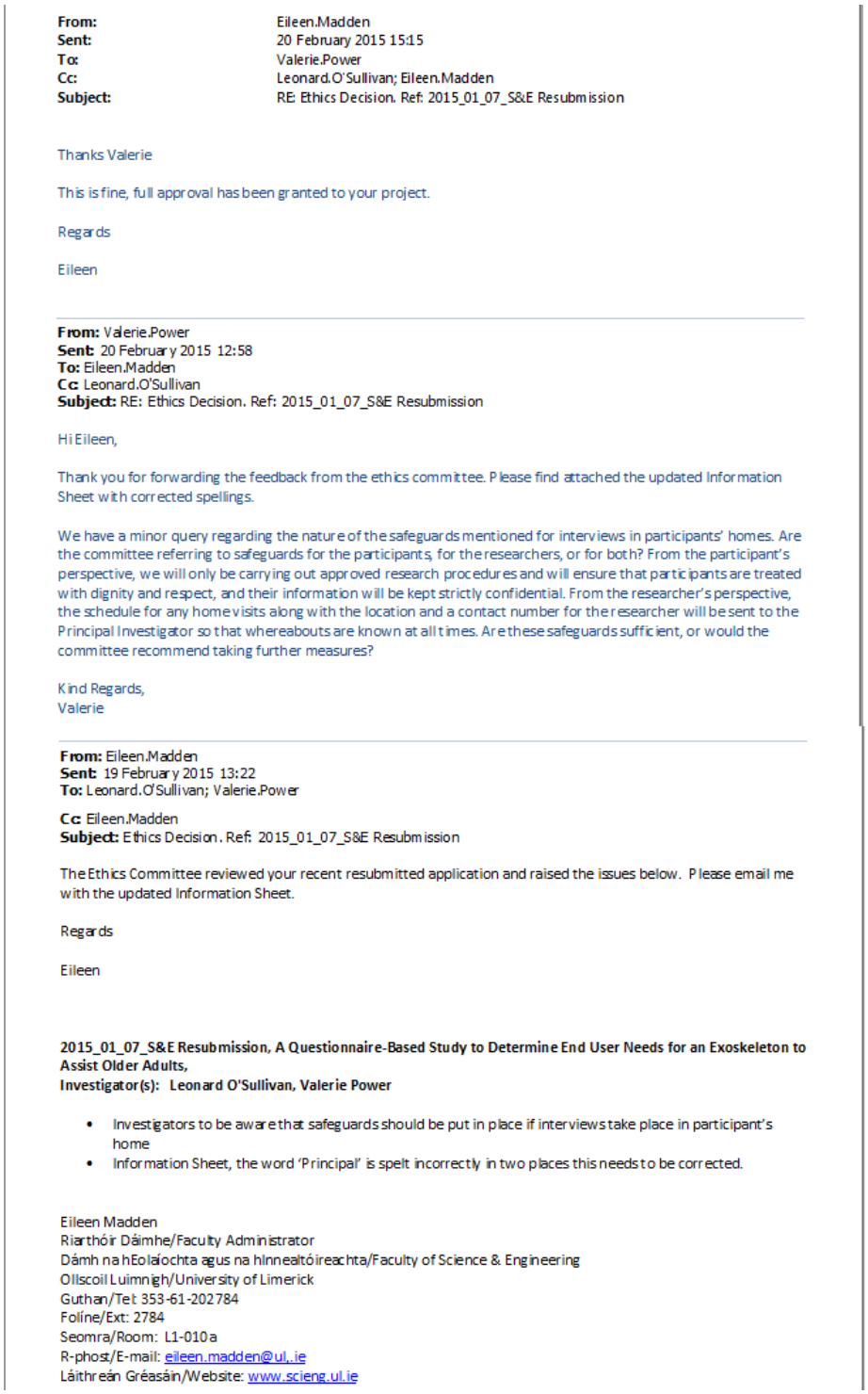
All questionnaires were completed anonymously. No information relating to a participant's identity was written on or attached to the hard copies of the completed questionnaires. Questionnaires were coded, according to the format described in D1.1, but no information linking this code to any individual participant was retained.

The anonymous data compiled from the questionnaire responses is being stored electronically in password-protected files on the hard drives of AXO-SUIT researchers only. Hard copies of completed questionnaires are being stored in a locked cabinet in the office of an AXO-SUIT researcher at the University of Limerick. Consent forms, including those containing contact details of participants who wish to be included on the End User Group contact list for further studies, are also being stored in a separate section of this locked cabinet to preserve anonymity. Only AXO-SUIT researchers have custody and access to the data collected. All data will be kept strictly anonymous for dissemination purposes.

In line with University policy, electronic data will be deleted from the hard drive on which it is stored and hard copy data will be shredded after 7 years.

4.3.4. Approval from Research Ethics Committee

Figure 2 shows the notification of approval for the Questionnaire 1 study from the UL Science and Engineering Research Ethics Committee (Reference: 2015_01_07_S&E Resubmission). The full application form is included in Appendix A.



From: Eileen.Madden
Sent: 20 February 2015 15:15
To: Valerie.Power
Cc: Leonard.O'Sullivan; Eileen.Madden
Subject: RE: Ethics Decision. Ref: 2015_01_07_S&E Resubmission

Thanks Valerie

This is fine, full approval has been granted to your project.

Regards

Eileen

From: Valerie.Power
Sent: 20 February 2015 12:58
To: Eileen.Madden
Cc: Leonard.O'Sullivan
Subject: RE: Ethics Decision. Ref: 2015_01_07_S&E Resubmission

Hi Eileen,

Thank you for forwarding the feedback from the ethics committee. Please find attached the updated Information Sheet with corrected spellings.

We have a minor query regarding the nature of the safeguards mentioned for interviews in participants' homes. Are the committee referring to safeguards for the participants, for the researchers, or for both? From the participant's perspective, we will only be carrying out approved research procedures and will ensure that participants are treated with dignity and respect, and their information will be kept strictly confidential. From the researcher's perspective, the schedule for any home visits along with the location and a contact number for the researcher will be sent to the Principal Investigator so that whereabouts are known at all times. Are these safeguards sufficient, or would the committee recommend taking further measures?

Kind Regards,
Valerie

From: Eileen.Madden
Sent: 19 February 2015 13:22
To: Leonard.O'Sullivan; Valerie.Power

Cc: Eileen.Madden
Subject: Ethics Decision. Ref: 2015_01_07_S&E Resubmission

The Ethics Committee reviewed your recent resubmitted application and raised the issues below. Please email me with the updated Information Sheet.

Regards

Eileen

2015_01_07_S&E Resubmission, A Questionnaire-Based Study to Determine End User Needs for an Exoskeleton to Assist Older Adults,
Investigator(s): Leonard O'Sullivan, Valerie Power

- Investigators to be aware that safeguards should be put in place if interviews take place in participant's home
- Information Sheet, the word 'Principal' is spelt incorrectly in two places this needs to be corrected.

Eileen Madden
Riarthóir Dáimhe/Faculty Administrator
Dámh na hEolaíochta agus na hInnealtóireachta/Faculty of Science & Engineering
Ollscoil Luimnigh/University of Limerick
Guthan/Tel: 353-61-202784
Folíne/Ext: 2784
Seomra/Room: L1-010a
R-phost/E-mail: eileen.madden@ul,.ie
Láithreán Gréasáin/Website: www.scieng.ul.ie

Figure 2. Notification of approval for Questionnaire 1 from UL S&E REC.

4.4. Sweden

4.4.1. Participants

Primary and secondary end users are informed of the opportunity to participate in AXO-SUIT via a combination of personal and professional networks, and public information sessions, as described in the following section. There is no exclusion policy for the Level 1 involvement in AXO-SUIT, and all interested persons are welcome to participate. Potential end user group members from countries other than those involved in the project are also included, as appropriate.

4.4.2. Recruitment Procedure

The foremost recruitment method adopted is a purposive sampling approach, whereby participants are selected through personal contacts of the researchers associated with UGAV, due to their interest in the area addressed by the project. The method of contact varies depending on the individual, but the project leader is always available to clarify and explain unresolved issues. Participants are also selected via municipality. Gävle Kommun is involved in the EXO-LEGS project as a partner. Gävle Kommun from time to time arranges public meetings in which researchers from Högskolan i Gävle hold presentations and Q&A sessions to provide information about the project, and all the necessary information regarding involvement in the project. Interested individuals then inform Gävle Kommun about their interest for involvement in the project.

UGAV has developed a process for engaging end users with the project. This aims to invite potential end users to participate in the project by providing information about the project and their role in it. The end users are signed up from several countries, not just Sweden. Information about the project has been prepared in different formats for use as appropriate e.g. Word files in English, Swedish, etc. have been prepared when it is distributed by introductory email and a Powerpoint presentation in English when the contact is face to face. The introductory material contains details of the person responsible for the research project, the organisation leading the project, the details of the research, and what their role will be in the project.

End user consent

After the introduction to the project, if the potential end users are interested to go ahead they are informed that their inputs made or data collected will be analysed and used for the project and related research activities only and not passed to other organisations. These inputs/data will be used in an anonymous manner and no correlation with specific individuals will be made. Once all the information has been provided and the end users have been given the opportunity to ask any questions to clarify issues they may have, they are asked to complete and sign the Consent Form (Appendix E) to participate. On this form, participants select the level of involvement they prefer to have with the project: Low, Medium or High (described in full in Appendix E).

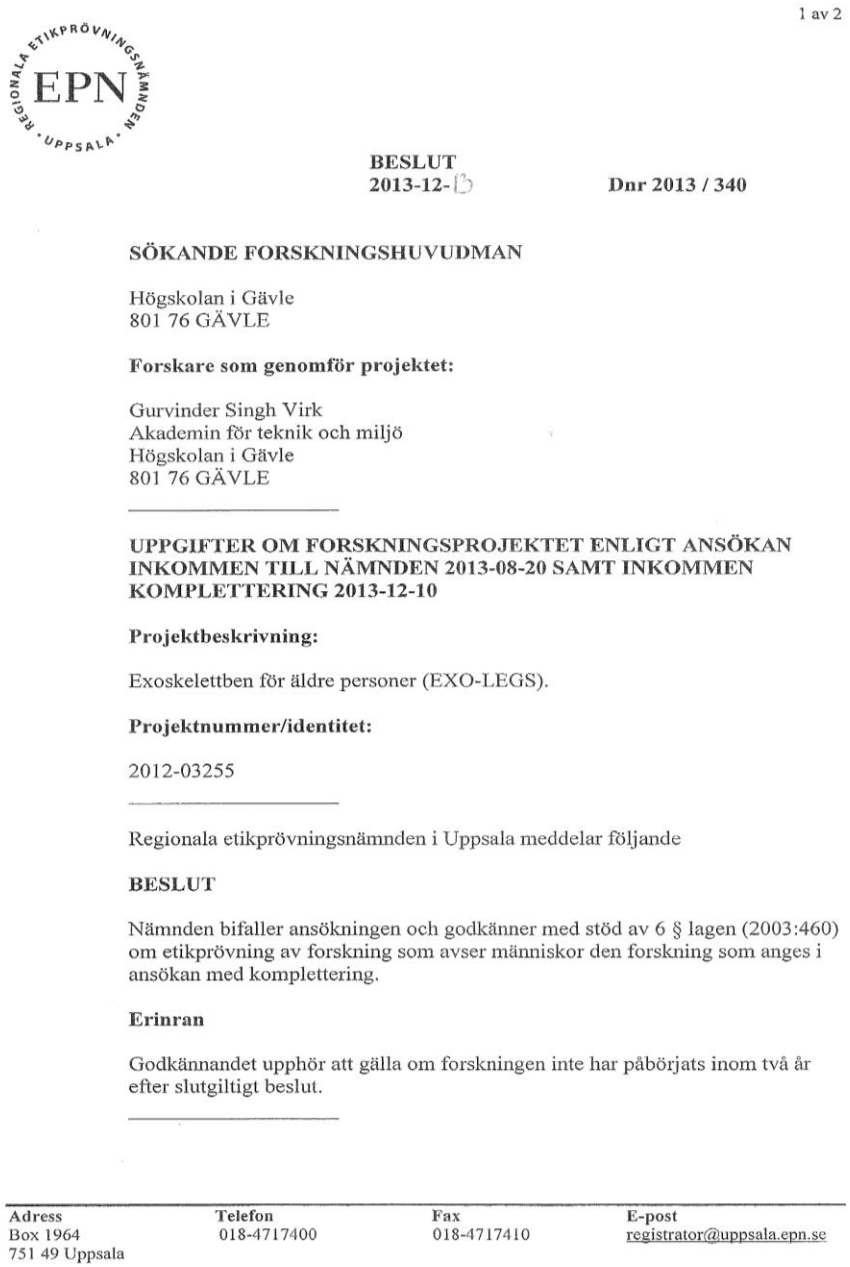
After the participants have given written consent, Högskolan i Gävle becomes the main contact with the end user via electronic mail or otherwise to request opinions of the end users via questionnaires on different issues in the project.

4.4.3. Data Storage and Confidentiality

All data on end users and their responses are recorded under coded pass-word protected computer systems where personal identifying information is replaced with a code. The code linking to individuals is kept in a secure place and destroyed after the research project has expired. All confidential aspects of the data collected is stored and processed by researchers only at Högskolan i Gävle, Sweden and is not be shared to any other partners, in Sweden or in any other country. All the procedures are followed in compliance with the data protection act of Sweden.

4.4.4. Approval from Research Ethics Committee

Approval letter obtained from Ethical Board Uppsala in December 2013 for Level 1 end user involvement in Sweden is shown in Figure 3 below. This approval was originally obtained for the EXO-LEGS project (AAL Call 4, www.exo-legs.org) but was deemed applicable to initial AXO-SUIT end user group activities also, following consultation with the Ethical Board Uppsala.



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REGIONALA ETIKPRÖVNINGSNÄMNDEN EPN UPPSALA

BESLUT
2013-12- **Dnr 2013 / 340**

SÖKANDE FORSKNINGSHUVUDMAN

Högskolan i Gävle
801 76 GÄVLE

Forskare som genomför projektet:

Gurvinder Singh Virk
Akademin för teknik och miljö
Högskolan i Gävle
801 76 GÄVLE

UPPGIFTER OM FORSKNINGSPROJEKTET ENLIGT ANSÖKAN INKOMMEN TILL NÄMNDEN 2013-08-20 SAMT INKOMMEN KOMPLETTERING 2013-12-10

Projektbeskrivning:

Exoskelettben för äldre personer (EXO-LEGS).

Projektnummer/identitet:

2012-03255

Regionala etikprövningsnämnden i Uppsala meddelar följande

BESLUT

Nämnden bifaller ansökningen och godkänner med stöd av 6 § lagen (2003:460) om etikprövning av forskning som avser människor den forskning som anges i ansökan med komplettering.

Erinran

Godkännandet upphör att gälla om forskningen inte har påbörjats inom två år efter slutgiltigt beslut.

Adress	Telefon	Fax	E-post
Box 1964 751 49 Uppsala	018-4717400	018-4717410	registrator@uppsala.epn.se

Figure 3. Letter of approval from Ethical Board Uppsala for Level 1 end user involvement in Sweden.

5. Ethics Processes for End User Involvement – Physical

As part of the user-centred design process being adopted in the AXO-SUIT project, further end user involvement will include further methods of seeking end user opinions (e.g. in relation to commercialisation aspects of the project) and also methods of allowing end users to view, interact with and test AXO-SUIT designs, test-rigs and prototypes. For methods which involve physical participation of end users, additional ethical considerations must be taken into account e.g. full understanding of participant roles for informed consent, safety, injury risks, potential for physical discomfort or embarrassment.

At present, the only physical involvement of participants in the AXO-SUIT project has been a study of human biomechanics undertaken at UoL to inform exoskeleton design specifications, based on priority end user functional activities identified in Questionnaire 1. End users have not yet been invited to physically interact with AXO-SUIT designs, test-rigs or prototypes at this stage.

However, since the upper and lower-body test-rigs are in an advanced stage of development, planning for such end user involvement is underway. Advance planning for such activities is crucial, since applying for and receiving approval from the relevant ethics committees can be a lengthy process.

The following sections will outline current plans for ethical procedures in relation to physical involvement of end users in the AXO-SUIT project.

5.1. Belgium

As described in Section 4.1, the current focus in Belgium ,remains on obtaining ethics committee approval for non-physical involvement of end users. Once the approval is received, recruitment for Questionnaire 1 will proceed as planned.

Participants who volunteer to take part in the Questionnaire 1 study will also be asked if they are willing to participate in further studies, questionnaires and trials. This will establish an end user group ready for participation in end user testing of the AXO-SUIT solution.

5.2. Denmark

Physical testing with AXO-SUIT exoskeleton prototypes in Denmark will be conducted at the robotics lab at AAU. The assisted activities and tests in the testing will be agreed by the AXO-SUIT consortium.

The participant recruitment and data storage will follow the procedures outlined in Section 4.2. AAU is currently preparing documents for the ethics application. All tests will only be conducted upon ethical approval by the Ethics Committee for Region Nordjylland (ECRN), which is expected in mid-2016.

5.3. Ireland

A small laboratory study was performed in UoL to collect 3D human motion and force data during simulated activities, based on the priority tasks identified by end users in Questionnaire 1. Details of the questionnaire results and the priority tasks selected are described in D1.3. The purpose of this study was to analyse human kinematics and kinetics during potential activities which AXO-SUIT UB, LB and FB exoskeletons may assist. Obtaining data on range of motion, movement velocity and torque requirements at various joints of the human body during such activities can then inform exoskeleton design specifications. An outline of the ethical considerations addressed in this study is provided in the following sections.

Further approval will need to be obtained prior to future studies involving end users, since approval may only be obtained from the S&E REC for a specific study protocol, regardless of whether the study entails physical or non-physical end user involvement.

5.3.1. Participants

Participants were healthy adults aged 18-55 years. All participants were required to be in good physical health. Exclusion criteria were:

- Current neurological or musculoskeletal condition or injury which impairs performance of activities of daily living.
- Current muscle soreness resulting from vigorous exercise in the previous 48 hours.
- Current use of medication which impairs performance of activities of daily living.
- Cognitive impairment which limits an individual's capacity to provide informed consent to participate.
- Vision and/or hearing impairments which limit an individual's capacity to safely follow instructions and perform the required activities.
- Non-English speaking participants, as the information sheet, consent form and instructions to participants will only be available in English.

Healthy adults without impairments were sought for this study as it was deemed appropriate to obtain data relating to high-functioning adults. It can be assumed that joint ranges of motion, velocities and torques will be greater among adults who do not have impairments that restrict their performances of activities. Therefore, obtaining data from such a sample will allow AXO-SUIT to be designed according to specifications for optimal user functioning.

5.3.2. Recruitment Procedure

Participants were recruited via email advertisement to all staff and students at UoL (the advertisement used is included in Appendix C). Since a considerable time demand was projected to be involved, participants were offered a multipurpose voucher as an incentive to participate. Individuals who contacted the research team to express interest in participation were forwarded the study information sheet and consent form. If individuals were still interested after receiving this information and were eligible to participate, an appointment to attend for testing at a convenient time was arranged with the researchers. All participants provided written informed consent prior to beginning any testing procedures.

5.3.3. Data Storage and Protection

Each participant's data was assigned an anonymous code, and no identifiable personal details are stored with this data. Participants' data will only be referred to by the assigned codes in any reports or publications arising from this study to ensure anonymity.

In keeping with University regulations, electronic data is being stored in password-protected files on the hard drive of an AXO-SUIT researcher's PC. No identifiable information is stored with this data. Consent forms are being stored in a locked cabinet at the University of Limerick, which is only accessible to the AXO-SUIT team. After 7 years, electronic data will be deleted from the hard drive on which it is stored and hard copy data will be shredded.

5.3.4. Approval from Research Ethics Committee

Figure 4 shows the notification of approval to conduct this study of human biomechanics at UoL. The final version of the expedited application form submitted to the S&E REC is included in Appendix D.

From: Eileen.Madden
Sent: 21 May 2015 15:30
To: Leonard.Browne; Valerie.Power
Cc: Eileen.Madden
Subject: Ethics Decision Ref: 2015_05_12

Follow Up Flag: Follow up
Flag Status: Completed

The Ethics Committee reviewed your recent application and has granted it full approval.

Regards

Eileen

2015_05_12_S&E Biomechanical analysis of human activities of daily living to inform assistive exoskeleton design,
Investigators: Leonard O Sullivan, Valerie Power
Approved as presented

Eileen Madden
Riarthóir Dáimhe/Faculty Administrator
Dámh na hEolaíochta agus na hInnealtóireachta/Faculty of Science & Engineering
Ollscoil Luimnigh/University of Limerick
Guthan/Tel: 353-61-202784
Folíne/Ext: 2784
Seomra/Room: L1-010a
R-phost/E-mail: eileen.madden@ul,.ie
Láithreán Gréasáin/Website: www.scieng.ul.ie

Figure 4. Notification of approval for study of 3D human motion and force data during selected activities.

5.4. Sweden

In Sweden, the actual physical testing of the developed exoskeletons in the AXO-SUIT project by the end users in a controlled environment is termed 'Level 2' end user involvement. This will involves additional ethical considerations and preparation of a further ethics application, including the following details:

- Inclusion/exclusion criteria for end user testing
- Assessment
    - Pre-screening of volunteers
    - Self-assessment
    - Medical assessment
- Information to be presented to test subjects on the test day
- Risk analysis and mitigation
- Summary of hazard notification
- Level 2 Consent
- Detailed processes for the functionalities to be tested
- Test assessment and measurements

UGAV have already developed these documents in EXO-LEGS project and obtained approval from Ethical Board Uppsala, thus the basis for completing the Level 2 application for AXO-SUIT already exists.

5.5. Ethical Considerations for Future Testing and Validation among End Users

As outlined in the previous section, numerous ethical considerations must be taken into account when planning for end user involvement in the physical testing and validation of AXO-SUIT. Closer interaction of users with AXO-SUIT test-rigs and/or prototypes necessitates more detailed consideration of potential hazards and identification of ways to mitigate risks.

The next planned phase of end user involvement will see primary end users being invited to view images and/or physical AXO-SUIT test-rigs where possible, to obtain some early user opinions on design on commercialisation aspects of AXO-SUIT. This will be a low-risk activity, limited to viewing rather than physically interacting with the system.

Later testing of upper-body and lower-body prototypes will incorporate physical interaction of human users with AXO-SUIT. Careful consideration of eligibility criteria for participants will be necessary in this phase, as will the provision of clear and concise information to all participants. Equally, testing protocols will need to be devised so as to ensure the collection of high-quality relevant data, while minimising participant discomfort and fatigue.

A detailed plan of testing procedures for AXO-SUIT upper-body and lower-body subsystems will be developed during Year 2 of the project These test procedures will investigate issues from technical perspectives e.g. functioning of motors and sensors, throughout to more user-centred issues such as usability and user acceptance. Full details of these procedures and the corresponding ethical considerations will be reported in Part 2 of this deliverable, due in Month 27.

6. Conclusions

The overall aim of Deliverable 1.2 is to formulate and implement ethical procedures in the engagement of end users throughout the AXO-SUIT project, specifically relating to end user involvement in the design, testing and validation stages.

As Part 1 of a two-part deliverable, this document has addressed the ethical considerations which have been of relevance throughout the first 15 months of the AXO-SUIT project. Ethics procedures that will apply to AXO-SUIT end users in all partner countries have been identified, both for non-physical and physical levels of involvement. The ethical considerations and processes involved in obtaining approval from all relevant ethics authorities for research conducted to date has also been described. In addition, this document has also outlined the preparations being undertaken to address ethical considerations in further research involving AXO-SUIT end users.

The contents of this document will inform ethical procedures throughout the remainder of the AXO-SUIT project, particularly in relation to the requirements and timelines for obtaining approval for proposed future studies which will include physical involvement of end users. In this way, AXO-SUIT will continue to implement timely and appropriate ethical procedures in the engagement of end users during the remainder of the AXO-SUIT design, testing and validation processes.

7. References

1. Röcker, C., *User-Centered Design of Intelligent Environments: Requirements for Designing Successful Ambient Assisted Living Systems*, in *Proceedings of the Central European Conference of Information and Intelligent Systems (CECIIS'13)*. 2013. p. 4-11.
2. AAL Programme *Guide for Applicants - Active and Assited Living Programme Call 2015*. 2015. available: http://www.aal-europe.eu/wp-content/uploads/2015/04/AAL-2015-Guide_for_Applicants_20150417.pdf [accessed 14th January 2016].

8. Appendix A: Denmark – Application Form on Data Protection

21/1/2015 Indtast

Anmeldelse af behandlinger der foretages for den offentlige forvaltning

Blankettype: Offentlig forvaltning

Anmeldelse af behandlinger der foretages for den offentlige forvaltning

Der søges samtidig om Datatilsynets tilladelse.

Bemærk! Hvor andet ikke udtrykkeligt er angivet, vil de oplysninger, der fremgår af anmeldelsesblanketten, blive offentliggjort i Datatilsynets Fortegnelse over anmeldte behandlinger. Fortegnelsen er offentligt tilgængelig på Datatilsynets hjemmeside. Felter markeret med * **skal** udfyldes.

- **Der skal indhentes forudgående udtalelse.**

1.Dataansvarlig myndighed	Navn Aalborg Universitet Adresse Frederiks Bajers Vej 5 For kommuner og regioner: Angiv kommune- eller regionskode. For øvrige myndigheder: Angiv ressortministerium Postnr. 9220 By Aalborg Ø Evt.J.nr./ID.nr. Kontaktperson Simon Christensen Tlf.nr. 30 70 26 61 E-mail sic@m-tech.aau.dk [X] Oplysningerne opbevares hos den dataansvarlige og/eller [ ] Oplysningerne opbevares hos databehandler Databehandlerens navn Databehandlerens adresse
2. Betegnelse og formål	Behandlingens betegnelse: Assisterende exoskelet egnet til ældre mennesker Behandlingens formål og evt. delformål: Aalborg Universitet koordinere et europæisk projekt (AXO- SUIT), som adresser det globale samfundsproblem med det stigende antal ældre borgere. Projektet har til formål at udvikle og fremstille et teknologisk hjælpemiddel (et exoskelet), der kan assistere de ældre borger i deres normale daglige aktiviteter, såsom at stå, gå, løfte og holde

https://anmeld.datatilsynet.dk/frontend/1.off.printasp?print=1

	genstande, skubbe og trække og ligende. For at resultaterne skal have nogen relevans i den virkelige verden, skal projektet indgå med virkelige slutbrugere til at bestemme, hvad der er behov for og løbende vurdere om det, der er leveret fra projekt, er hvad der blev anmodet om. Derfor oprettes en slutbruger gruppe AEUG-DK (AXO-SUIT End- User Group i Danmark), som består af primære, sekundære og tertiære slutbrugere. Formålet med denne gruppe er at få indblik i hvilke tanker , holdninger og krav mulige bruger og industrien har til exoskelettet for at det kan blive et reelt produkt. Her tænkes både på funktionelle og design krav til exoskelettet, samt muligheder for markedsføring af produktet. Behandlingen skal udelukkende finde sted i videnskabeligt eller statistisk øjemed [X] Ja [ ] Nej Behandlingen skal udelukkende finde sted med henblik på at føre et retsinformationssystem [ ] Ja [X] Nej
3. Generel beskrivelse	Følgende typer af behandling indgår: Medlemmerne af AEUG-DK har mulighed for at deltage i projektet i tre niveauer: Niveau 1 (Lav): Her besvarer medlemmet på spørgeskemaer via e-mail eller interview. Niveau 2 (Mellem): Her stiller medlemmet op til mere detaljerede interviews og diskussioner. Niveau 3 (Høj): Her stiller medlemmet op til afprøve og teste udviklede prototyper Aalborg Universitet indsamler, registrerer og anonymiserer data fra medlemmerne af AEUG- DK. Den anonymiserede data indsamlet fra udelukkende Niveau 1 deles efterfølgende med de andre partner i AXO-SUIT projektet. Der vil blive foretaget samkøring/sammenstilling af oplysninger i kontroløjemed [X] Nej [ ] Ja, med hjemmel i følgende lov: Der indgår manuelle registre i behandlingen [ ] Ja [X] Nej

	Der påtænkes truffet afgørelser udelukkende på grundlag af elektronisk databehandling [X] Ja [ ] Nej Der behandles følgende følsomme oplysninger: [ ] Racemæssig eller etnisk baggrund [ ] Politisk overbevisning [ ] Religiøs overbevisning [ ] Filosofisk overbevisning [ ] Fagforeningsmæssige tilhørsforhold [X] Helbredsforhold, herunder misbrug af medicin, narkotika, alkohol m.v. [ ] Seksuelle forhold Der behandles følgende andre oplysninger om enkeltpersoners rent private forhold: [ ] Strafbare forhold [ ] Foreningsmæssige forhold [ ] Væsentlige sociale problemer [ ] Andet
4.Kategorier af registrerede og oplys-ningstyper	Der behandles oplysninger om følgende kategorier af personer: A) De primære slutbrugere er ældre borgere, som vil ende med at bruge produkter fra AXO-SUIT projektet B) De sekundære slutbrugere er venner og familie til primære slutbrugere eller professionelle eksperter indenfor forskellelige grene af sundhedspleje og teknologi udvikling C) De tertiære slutbrugere er private eller offentlige organisationer, institutioner, forskringsselskaber eller ligende. D) E) F) Der behandlers følgende typer af oplysninger om de ovenfor angivne kategorier af personer: ad A) Baggrundsspørgsmål, som køn, alder, højde, vægt, profession, civilstand, bopæl og interesse for og/eller kendskab til teknologi. Spørgsmål om helbredsforhold, som typiske daglige aktiviteter (både i hjemme, udendørs og ved sociale events) og evnen til at udføre dem, smerter og ubehag og generel førelighed/mobilitet. Holdningsspørgsmål angående design af exoskelettet og projektets kommercielle potential. Slutteligt vil der også spørges om

	forventningerne til produktet. ad B) Baggrundsspørgsmål, som køn, alder, profession, interesse for og/eller kendskab til teknologi og relation til mulige primære slutbruger. Holdningsspørgsmål angående design af exoskelettet, projektets kommercielle potential og mulig brug i andre områder. Slutteligt vil der også spørges om forventningerne til produktet. ad C) Baggrundsspørgsmål, som køn, alder, profession, interesse for og/eller kendskab til teknologi og relation til mulige primære slutbruger. Holdningsspørgsmål angående design af exoskelettet, projektets kommercielle potential og mulig brug i andre områder. Slutteligt vil der også spørges om forventningerne til produktet. ad D) ad E) ad F)
5. Modtagere	Oplysningerne kan overføres til følgende modtagere eller kategorier af modtagere: Anonymiseret data fra Niveau 1 (Lav) deles med: Welldana A/S (Danmark), Högskolan i Gävle (Sverige), Bioservo Technologies AB (Sverige), Hjälpmedelsteknik Sverige (Sverige), University of Limerick (Irland), MTD Precision Engineering Ltd (Irland) og COMmeto bvba (Belgien)
6. Tredjelande	Der påtænkes overført oplysninger til tredjelande: [X] Nej [ ] Ja, overførslen sker med følgende formål:
7. Sikkerhed	Der træffes sikkerhedsforanstaltninger, som beskrevet i Justitsministeriets bekendtgørelse nr. 528 af 15.juni 2000 kapitel 1 og 2 [X] Ja [ ] Nej Der træffes sikkerhedsforanstaltninger som beskrevet i Justitsministeriets bekendtgørelse nr. 528 af 15. juni 2000 kapitel 3 [ ] Ja [X] Nej Evt. yderligere sikkerhedsforanstaltninger:
8. Påbegynd-else	Tidspunkt for påbegyndelse af behandling: Dato 1. marts 2015

9.Sletning	Tidspunkt for sletning af oplysninger: 1. oktober 2020
10. Underskrift	Offentliggøres ikke i fortegnelsen Dato Navn Shaoping Bai
Bemærk: Ændringer skal meddeles Datatilsynet. Myndigheden skal selv opbevare en kopi af anmeldelsen.	

Følgebrev til Datatilsynet:

9. Appendix B: Denmark – Data Protection Approval

AALBORG UNIVERSITET

Institut for Mekanik og Produktion
Simon Christensen
Fibigerstræde 16
9220 Aalborg Ø

Kontraktenheden
Niels Jernes Vej 10
Postboks 159
9100 Aalborg

Sagsbehandler:
Kathrine Tvorup Pajkes
Telefon: 9940 8084
Email: ktp@adm.aau.dk

Sagsnr.: 2013-871/10-0201

Udtalelse vedr. behandling af personoplysninger anmeldt under AAU's fællesanmeldelse til Datatilsynet af 18. september 2015 (Datatilsynets j. nr. 2015-509-00007)

Du har den 7. oktober 2015 foretaget anmeldelse til Kontraktenheden af behandling af personoplysninger udelukkende i videnskabeligt eller statistisk øjemed.

Det fremgår af anmeldelsen, at behandlingen nærmere drejer sig om indsamling, registrering, opbevaring, analyse og sletning af helbredsoplysninger i relation til forskningsprojektet Assisterende EXO skelet egnet til ældre mennesker.

Kontraktenheden kan i den anledning oplyse, at behandlingen af de pågældende personoplysninger kan påbegyndes, og at du i den forbindelse skal opfylde de krav til behandlingen, som følger af vedlagte bilag 1. Kontraktenheden gør endvidere opmærksom på, at behandling alene må ske frem til det i anmeldelsen angivne sluttidspunkt af 1. oktober 2020. Herefter skal de pågældende personoplysninger slettes.

Med venlig hilsen

Kathrine Tvorup Pajkes

AALBORG UNIVERSITET

Bilag 1

Krav til behandling og datasikkerhed

Den projektansvarlige forsker eller forskergruppe skal sikre, at behandling af personoplysninger sker i overensstemmelse med Persondataloven, herunder kravene i Sikkerhedsbekendtgørelsen (Justitsministeriets bekendtgørelse nr. 528 af 15. juni 2000), Aalborg Universitets sikkerhedsinstruks.

Derudover skal den projektansvarlige forsker eller forskergruppe sikre, at neden følgende vilkår overholdes:

Behandling

- Personoplysningerne må ALENE anvendes inden for det pågældende videnskabelige og/eller statistiske formål angivet i anmeldelsen. De pågældende personoplysninger må således IKKE indgå i administrativ eller konkret sagsbehandling.

- Behandling af personoplysningerne må KUN foretages af den projektansvarlige forsker eller på foranledning af den projektansvarlige forsker og på dennes ansvar.

- Den projektansvarlige forsker skal sikre, at der alene behandles personoplysninger, der er omfattet af anmeldelsen og at personoplysningerne hverken kommer til uvedkommendes kendskab eller misbruges.

- Den projektansvarlige forsker skal sikre, at der ikke behandles urigtige eller vildledende personoplysninger. Urigtige eller vildledende personoplysninger, eller personoplysninger, som er behandlet i strid med persondataloven eller disse krav, skal berigtiges eller slettes.

- Personoplysningerne skal i videst muligt omfang behandles i en form, hvor de ikke er umiddelbart personhenførbare, fx i krypteret form eller under et løbenummer i stedet for under personnummer. Krypteringsnøgle eller kodenøgle til løbenumre mv. skal opbevares forsvarligt og adskilt fra personoplysningerne.

AALBORG UNIVERSITET

- Der må ikke føres edb-registre med oplysninger om politiske forhold, som ikke er offentligt tilgængelige.

- Den projektansvarlige forsker skal sikre, at personoplysningerne ikke hændeligt eller ulovligt tilintetgøres, fortabes eller forringes (eksempelvis ved at foretage regelmæssige sikkerhedskopieringer).

- Hvis behandling af personoplysninger finder sted på it-udstyr uden for Aalborg Universitets lokaliteter, eller finder sted på it-udstyr, som ikke er en del af universitetets almindelige it-system, så skal den projektansvarlige forsker sikre de fornødne sikkerhedsforanstaltninger.

- Den projektansvarlige forsker skal ved overførsel af personoplysninger via internet eller andet eksternt netværk sikre, at der træffes de fornødne sikkerhedsforanstaltninger mod, at personoplysningerne kommer uvedkommendes kendskab. Herunder skal anvendes kryptering, hvis personoplysningerne overføres via internettet eller andre åbne net, og sikring af sikkerhed for autenticitet (afsenders og modtagers identitet) og integritet (de afsendte personoplysningers ægthed) skal ske i fornødent omfang ved anvendelse af passende sikkerhedsforanstaltninger.

- Ved anvendelse af interne net skal det sikres, at uvedkommende ikke kan få adgang til personoplysningerne.

Opbevaring

- Personoplysningerne må ikke opbevares på en måde, der giver mulighed for at identificere de personer som personoplysningerne omhandler i et længere tidsrum end det, der er nødvendigt af hensyn til projektets gennemførelse.

- Den projektansvarlige forsker er til enhver tid ansvarlig for at sikre, at personoplysningerne, uanset om de forefindes i elektronisk eller fysisk form, opbevares i overensstemmelse med nedennævnte principper:

    - Lokaler, der benyttes til opbevaring eller behandling af personoplysninger skal være indrettet således, at uvedkommende ikke kan få adgang.
    - Personoplysninger, der opbevares elektronisk, skal opbevares på en sikker og forsvarlig måde, og således at uautoriserede personer ikke har adgang hertil.
    - Der skal anvendes adgangskode (password) for at få adgang til pc'er og andet elektronisk udstyr med personoplysninger. Kun de personer, der skal have adgang, må få en kode. De personer, der har adgangskode må ikke overlade koden til andre eller lade den ligge, så andre kan se den. Koden skal udskiftes mindst én gang om året, og når forholdene tilsiger det.

AALBORG UNIVERSITET

- Hvis personoplysningerne lagres på udtagelige og mobile datamedier (eksempelvis USB-nøgler) skal der sikres mod, at uvedkommende kan tilgå oplysningerne på det bærbare datamedie i tilfælde af, at det mistes/stjæles (eksempelvis ved anvendelse af adgangskode og kryptering). Alternativt skal de udtagelige datamedier opbevares forsvarligt aflåst og således, at uvedkommende ikke kan få adgang til personoplysningerne.
- Adgang til personoplysningerne skal begrænses til personer, der har et sagligt behov for adgang. Det skal være så få personer som muligt.
- Der skal foretages logning (maskinel registrering) af alle anvendelser af personoplysningerne. Logningen skal mindst indeholde oplysning om tidspunkt, bruger, type af anvendelse og angivelse af den person, de anvendte oplysninger vedrørte, eller det anvendte søgekriterium. Såfremt personoplysningerne forinden er blevet krypterede eller erstattet med et løbenummer el.lign. så skal der alene foretages logning af tidspunkt for behandling og pågældende bruger. Loggen skal opbevares i 6 måneder, hvorefter den skal slettes.

Databehandlere

- Såfremt det i forbindelse med projektet er nødvendigt, at personoplysningerne behandles af en eller flere eksterne samarbejdsparter, så skal der inden personoplysningerne udleveres til samarbejdsparten, indgås en databehandleraftale mellem Aalborg Universitet og den eller de pågældende eksterne samarbejdsparter. Skabelon til Databehandleraftale kan fås ved kontakt til Kontraktenheden ved AAU. Databehandleraftalen skal inden underskrift godkendes af Kontraktenheden ved AAU.

Formidling

- Formidlingen af projektets resultater skal ske på en sådan måde, at det ikke er muligt for udenforstående at identificere enkeltpersoner.

Projektets afslutning

- Personoplysninger skal ved projektets afslutning enten slettes, anonymiseres eller tilintetgøres på en sådan måde, at det efterfølgende ikke er muligt at genetablere de pågældende personoplysninger.

- Alternativt kan personoplysningerne overføres til opbevaring i arkiv efter reglerne i arkivlovgivningen.

AALBORG UNIVERSITET

Videregivelse

- Personoplysningerne må kun efter forudgående tilladelse fra Kontraktenheden ved AAU videregives/udleveres til tredjemand. Sådan tredjemand må alene anvende de pågældende personoplysninger i videnskabeligt og/eller statistisk øjemed.

NB! Vær opmærksom på, at overførsel af et forskningsprojekt i forbindelse med den projektansvarliges evt. jobskifte er videregivelse i persondatalovens forstand.

10. Appendix C: Ireland – Questionnaire 1 Ethics Application

Faculty of Science & Engineering Research Ethics Committee
Full Application Form

1	**Title of Research Project**
	A Questionnaire-Based Study to Determine End User Needs for an Exoskeleton to Assist Older Adults

2	**Period for which approval is sought**
	February 2015 (date on which approval is obtained) to 31st December 2015

3 Project Investigators

3a Principal Investigator (Supervisor)	
Name	Dr Leonard O'Sullivan
Department	Design and Manufacturing Technology
Position	Senior Lecturer Ergonomics and Human Factors
Qualifications	PhD, FIES, MIEHF, MHFES, MIOSH
Telephone Number	+353 61 234249
e-mail address	Leonard.O'Sullivan@ul.ie

3b Other Investigators		
Name	**Qualifications & Affiliation**	**Signature**
Valerie Power	PhD, BSc; Department of Design and Manufacturing Technology	

4 Head of Department(s)

I have read through this application and am aware of the possible risks to participants involved in this study.
I hereby authorise the Principal Investigator named above to conduct this research project.

Name	**Department**	**Date**	**Signature**
Dr Seamus Gordon	Design and Manufacturing Technology		

5 Study Descriptors

Please indicate the terms that apply to this research project			
Healthy Adults	☑	Healthy Children (< 18 yrs.)	☐
Patient Adults	☐	Patient Children (< 18 yrs.)	☐
'Potentially Vulnerable' Adults	☐	'Potentially Vulnerable' Children	☐
Physical Activity	☐	Questionnaire/Interview	☑
Medical Devices / Drugs	☐	Video Recording/Photography	☐
Food/Drink Supplementation	☐	Collection of Personal Details	☐
Measure Physical in Nature	☐	Measure Psychological in Nature	☐
Body Tissue Samples	☐	Observational	☐
Body Fluids Samples (e.g. blood)	☐	Record Based	☐

6 Project Design

6a Justification for Research Project *(Include reference to published work)*

For ageing individuals, declining mobility and capacity to perform activities of daily living can lead to loss of independence, decreased engagement in the community and reductions in quality of life (Gill et al. 1995; Gill & Kurland 2003). As such, solutions that can effectively and affordably supplement older adults' diminishing functional capacity and thus facilitate maintained independence and social participation over time are urgently required. One group of potential solutions are exoskeletons – wearable devices which can provide users with active assistance to augment their performances of functional activities (Dollar & Herr 2008).

The proposed study is intended to be carried out as part of the AXO-SUIT project (www.axosuit.eu), which is funded by the European Commission under the Ambient Assisted Living Joint Programme Initiative Call 6. The AXO-SUIT project aims to design, develop, and validate upper-, lower- and full-body assistive exoskeletons for older adults, which comfortably fit the human body and actively help the wearer in their daily activities and voluntary occupations. A crucial component of this project is the integration of end users' perspectives throughout the design, development and validation processes (Shah et la. 2009). As such, data is planned to be gathered from questionnaire studies of end users across four European countries (Belgium, Denmark, Ireland, and Sweden) to inform the design features and functional requirements of the AXO-SUIT exoskeletons.

The proposed questionnaire study specifically aims to identify the functional requirements of a group of primary end users (i.e. older adults) in Ireland. The findings of this study will be used to formulate functional specifications for the AXO-SUIT lower-body and upper-body sub-systems, which will ensure that the AXO-SUIT prototypes will provide for the specific mobility, reaching and handling needs of end users. The data obtained will also be used to formulate the assessment metrics to be used in evaluating the solutions produced from technical, non-technical and users' viewpoints. These findings are anticipated to not only inform subsequent work undertaken as part of the AXO-SUIT project, but also to provide valuable insights into the perspectives and needs of end users in relation to assistive exoskeletons in general.

This study is an amended version of the study bearing the same title which was granted approval in January 2015 (Reference: 2015_01_07_S&E). Resubmission is required as substantive changes have been made to the questionnaire design following meetings with the AXO-SUIT consortium. In addition, the current application makes provision for participants in this study to be shortlisted for invitation to subsequent questionnaire studies in relation to the AXO-SUIT project, which was not included in the previous application.

References

Gill, T. M., Williams, C. S. and Tinetti, M. E. (1995) 'Assessing risk for the onset of functional dependence among older adults: the role of physical performance', *Journal of the American Geriatrics Society,* 43(6), 603-609.

Gill, T. M. and Kurland, B. (2003) 'The Burden and Patterns of Disability in Activities of Daily Living Among Community-living Older Persons', *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences,* 58(1), M70-M75.

Dollar, A. M. and Herr, H. (2008) 'Lower Extremity Exoskeletons and Active Orthoses: Challenges and State-of-the-Art', *Robotics, IEEE Transactions on,* 24(1), 144-158.

Shah, S. G. S., Robinson, I. and AlShawi, S. (2009) 'Developing medical device technologies from users' perspectives: a theoretical framework for involving users in the development process', *International journal of technology assessment in health care,* 25(04), 514-521.

6b Hypotheses or questions to be answered

The objectives of this questionnaire study are:

1) To identify the most pertinent functional assistance requirements of potential end users of the AXO-SUIT exoskeleton in terms of lower-body, upper-body, and full-body activities
2) To obtain preliminary indicators of end users' use and attitudes towards technology and assistive devices, particularly exoskeletons
3) To ascertain end users' current health and functional status, in order to provide context to the attitudes and functional requirements identified

6c Plan of Investigation

Potential participants will be sourced as described in Section 7a.

Individuals who contact the research team to express an interest in participating will be invited to attend a once-off appointment to complete the questionnaire. The date, time and location of this appointment will be agreed upon between the participant and the research team. Participants may opt to complete the questionnaire:

1. In their own home
2. In the venue at which their community group meets, if that venue is available at a suitable date and time and is convenient for participants to attend.
3. At the University of Limerick, in room number F2-022.

When attending the appointment, participants will be provided with an Information Sheet (Appendix 1), given the opportunity to ask questions about the study and, if they are willing to take part, will be asked to sign a Consent Form (Appendix 2). If informed consent is provided, participants will then be asked to complete the questionnaire. The entire appointment is expected to be of approximately 40 minutes in duration.

As part of the Consent Form (Appendix 2), participants will be asked if they would like to be invited to participate in any future questionnaire studies that may arise as part of the AXO-SUIT project, and to provide a contact telephone number and/or email address if they so wish. This section is optional, and participants may opt in, opt out, or leave this section incomplete. Separate ethics committee approval will be sought for any further questionnaire studies, and participants will not be contacted with invitations to participate until approval has been obtained for such studies. Separate informed consent will also be required prior to participation in further studies.

6d Research procedures

The questionnaire is composed of six sections:

- Sections 1-3 ask participants to rank their functionality requirements for lower body, upper body and full body assistance
- Section 4 asks participants basic details about their age, gender, height, weight and residential status. This section also includes a short standardised assessment tool to establish participants' current health status, the EQ-5D-5L instrument (Herdmann et al. 2011).
- Section 5 asks participants open-ended questions to establish common activities in the home, around the home/garden, and in the community that participants have difficulty performing or do not perform, as well as the reasons why.
- Section 6 includes questions on participants' use of technology (including email, as an indicator of possible future questionnaire distribution methods) and assistive devices, and their perceptions of the term 'exoskeleton'.

The questionnaire will be completed in the presence of a post-doctoral researcher who will explain the questions and answering procedures to participants, as required. The purpose of this method of administration is to ensure that participants understand the contents of the questionnaire and provide complete responses, as well as to facilitate participation for those with mild visual impairments, poor literacy skills, or health conditions which may limit their ability to provide written responses to the questionnaire. It is anticipated that the questionnaire will take a maximum of 25 minutes to complete.

Reference

Herdman, M., Gudex, C., Lloyd, A., Janssen, M. F., Kind, P., Parkin, D., Bonsel, G. and Badia, X. (2011) 'Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)', *Quality of Life Research,* 20(10), 1727-1736.

6e Associated risks to subjects

There is a low level of risk to participants in this study. The questionnaire includes questions regarding participants' current health status and ability to perform common functional activities. Some older adults may feel uncomfortable disclosing this information. To minimise such discomfort, potential participants will be fully informed of all procedures prior to participating and may choose to decline participation. Participants may also cease their participation in the study at any time without providing a reason.

6g Statistical approach to be used and source of any statistical advice

The majority of questions included in the questionnaire will comprise of rankings or ratings on Likert scales. Responses to these questions will be assigned numerical values, pooled across all responses obtained and descriptive statistics will be used to illustrate levels of agreement across the sample as a whole. Open-ended questions will be analysed by creating appropriate categories, coding the responses, identifying major themes and exploring patterns or trends among categories. This analysis will be carried out by a post-doctoral researcher with previous experience in analysing questionnaire data.

6h Location(s) of Project

The study will be carried out at the location of the participant's choosing, from the following choice of locations:

1. The participant's home
2. The meeting place of the community group through which the participant(s) was recruited
3. The University of Limerick, room F2-022

7 Subjects

7a How will potential research participants be sourced and identified?

Potential participants will be sourced via local community groups/social clubs for older adults in Limerick City and County, North Tipperary and East Clare. Publicly available contact details will be used to contact the organisers of such groups. The group organisers will be invited by the researchers:

a) to notify their members of the opportunity to participate in this study, or
b) to have a member of the research team attend a group meeting to provide a brief 5-10 minute introduction and invitation to participate, or
c) to decline to participate should the organiser deem the study to be inconvenient or inappropriate for their members.

Should options a) or b) be selected, contact details for the research team will be provided to the group's members, and any individuals who wish to participate may contact the researchers to express their interest.

7b Will research participants be recruited via advertisement (poster, e-mail, letter)?

YES ☐ ☑ **NO**

If YES, please provide details below, or attach the recruitment advertisement if written.

7c How many participants will be recruited?

Male	**25**	**25**	**Female**

Provide further information if necessary

Approximately 40 complete responses to the questionnaire are required, thus a maximum of 50 participants are expected to be recruited to account for potential withdrawals and/or incomplete responses.

7d What are the principal inclusion criteria? (*Please justify*)

- Adults aged 55 years and over – These individuals represent the anticipated primary end users of the exoskeleton which is planned for development.
- English-speaking – The questionnaire will be provided to participants in English only, as translation facilities are not available.

7e **What are the principal exclusion criteria?** (*Please justify*)

- Cognitive impairment – May limit the individual's capacity to provide informed consent to participate and/or to complete the written questionnaire
- Severe vision and hearing impairments – Information about the study and the questionnaire itself will be provided in written format and/or verbally, thus individuals who cannot access information in these formats will be excluded from participation.

7f **What is the expected duration of participation for each participant?**

It is anticipated that the total duration of participation for each participant will be approximately 40 minutes:

- 10-15 minutes introduction to research study, reading information sheet and completing consent form
- 25-30 minutes maximum to complete the questionnaire

7g **What is the potential for pain, discomfort, embarrassment, changes to lifestyle for the research participants?**

No potential for pain, discomfort or changes to lifestyle is foreseen for participants. There may be potential for some embarrassment among participants when answering questions relating to their current health status or ability to perform some activities of daily living. To limit this, participants will be assured that all questionnaire data will be stored anonymously, and will be free to cease participation in the study at any time.

7h **What arrangements have been made for participants who might not adequately understand verbal explanations or written information in English?**

Such individuals will not be eligible to participate in this study, as per Section 7d.

7i **Have arrangements been made to accommodate individuals who do not wish to participate in the research? (NB This mainly relates to research taking place in a classroom setting)**

Yes ☐ **No** ☐ **N/A** ☑

If Yes
Please state what these arrangements are:

7j **Will subjects receive any payments or incentives, or reimbursement of expenses for taking part in this research project?**

YES ☐ ☑ **NO**

If YES, please provide details below, and indicate source of funding:

8 Confidentiality of collected data

8a **What measures will be put in place to ensure confidentiality of collected data?**
All questionnaires will be completed anonymously. No information relating to a participant's identity will be written on or attached to the hard copies of the completed questionnaires. Questionnaires will be numbered sequentially (I01, I02 etc.) for the purposes of collating the data, but no information linking this number to an individual participant will be retained.

Contact details of participants who wish to be included on contact lists for any further studies will be stored separate to the completed questionnaires to preserve anonymity.

8b **Where will data be stored, i.e. Room Number?**

The anonymous data compiled from the questionnaire responses will be stored electronically in password-protected files on the hard drives of the investigators listed in Section 3. Hard copies of completed questionnaires will be stored in a locked cabinet in the Principle Investigator's office at the University of Limerick (F2-022). Contact details of participants who wish to be included on contact lists for further studies will be stored in the same location in a locked cabinet, but separate to the questionnaires to ensure anonymity.

8c **Who will have custody and access to the data?**
The researchers listed in Section 3 above will have custody and access to the data collected. All data will be kept strictly anonymous for dissemination purposes.

8d **Data to be stored for 7 years after publication:** How do you propose to store the information once the project is completed? Will the file/computer be password protected?

Electronic data will be stored in password-protected files on the hard drive of the Principle Investigator. Consent forms and hard copies of completed questionnaires will be retained in a locked cabinet in the Principle Investigator's office at the University of Limerick. After 7 years, electronic data will be deleted from the hard drive on which it is stored and hard copy data will be shredded.

Where will the information be stored (room number):

F2-022

9 Drugs or Medical Devices

Are Drugs or Medical Devices to be used?

YES ☐ ☑ **NO**

If YES please complete 9a to 9c

9a **Details of the Drugs or Devices (including name, strength, dosage, route of administration)**
N/A

9b **Details of Clinical Trial Certificate, Exemption Certificate or Product Licence (The Product Licence must cover the proposed use in the Project)**
N/A

9c **Details of any Risks (Both to subjects and staff; indicate current experience with the drug or device)**
N/A

10 Insurance Cover

Insurance cover is required for all research carried out by UL employees. Principal Investigators/Supervisors should carefully view the University's 'Guidelines on Insurance Cover for Research' document and the University's Insurance cover to ascertain if their proposed research is covered. These documents are available at www.ul.ie/insurance.

Where any query arises about whether or not proposed research is covered by insurance, the Principal Investigator/Supervisor must contact the University's Insurance Administrator at cliona.donnellan@ul.ie to confirm that the required level of insurance cover is in place.

Please indicate by way of signature that the research project is covered by UL's insurance policies:

PI/Supervisor signature: _____

11 Information Documents

Please note: failure to provide the necessary documentation will delay the consideration of the application. Please complete the checklist below:

Documents	***Included?***		
Participant Information Sheet	**YES**	☑	**N/A** ☐
Participant Consent From	**YES**	☑	**N/A** ☐
Parent/Guardian Information Sheet	**YES**	☐	**N/A** ☑
Parent/Guardian Consent Form	**YES**	☐	**N/A** ☑
School Principal Information Sheet	**YES**	☐	**N/A** ☑
School Principal Consent Form	**YES**	☐	**N/A** ☑
Teacher Information Sheet	**YES**	☐	**N/A** ☑
Teacher Consent Form	**YES**	☐	**N/A** ☑
Questionnaire/Interview/Survey Questions	**YES**	☑	**N/A** ☐
Recruitment Letters/Advertisements/Emails etc.	**YES**	☐	**N/A** ☑
Acceptance of UL Child Protection Form	**YES**	☐	**N/A** ☑

Please ensure any additional documents are included with this application.
These should be attached as a single document and included in the e-mail submission.

12 Declaration

The information in this application form is accurate to the best of my knowledge and belief, and I take full responsibility for it.

I undertake to abide by the ethical principles outlined in the Science & Engineering Research Ethics Committee guidelines.

If the research project is approved, I undertake to adhere to the study protocol without unagreed deviation, and to comply with any conditions sent out in the letter sent by the Science & Engineering Research Ethics Committee notifying me of this.

I undertake to inform the Science & Engineering Research Ethics Committee of any changes in the protocol, and to submit a Report Form upon completion of the research project.

Name of Principal Investigator	**Dr Leonard O'Sullivan**
Signature of Principal Investigator (or Head of Department*)	
Date	**04/02/2015**

****Please note:*** *where the Principal Investigator is not a permanent employee of the University of Limerick, the relevant Head of Department should sign this declaration.*

1. Once completed, this form along with a single document containing any additional documentation should be submitted **electronically** to the Faculty Office, Science & Engineering at SciEngEthics@ul.ie

2. In addition, **1 copy** of the fully signed application and any attachments should be submitted to:
   The Secretary,
   Faculty of Science & Engineering Research Ethics Committee,
   University of Limerick

UNIVERSITY *of* LIMERICK

OLLSCOIL LUIMNIGH

INFORMATION SHEET

A Questionnaire-Based Study to Determine End User Needs for an Exoskeleton to Assist Older Adults

You are invited to take part in the research project named above which is being conducted by researchers from the University of Limerick.

What is the study about?

The study aims to find out the needs of older adults for assistance and assistive devices in order to carry out a range of daily activities in the home and in the community. This information will be used to help in the design of a wearable assistive device for older adults (an "exoskeleton").

What do I have to do?

If you decide to participate, you will be asked to:

- Contact the researchers to arrange an appointment at a date, time and location that is convenient for you.
- Complete the consent form attached to this information letter.
- Complete a questionnaire which asks questions about:
    - Basic details about yourself and your general health status
    - How important you think it is to receive assistance with specific lower body, upper body and full body functions
    - Daily activities which you currently need assistance to perform
    - Your opinions on using technology and assistive devices

How long will it take?

You will be asked to attend 1 appointment to complete the questionnaire. This appointment is expected to last a maximum of approximately 40 minutes.

Who else is taking part?

We are seeking approximately 40 people aged 55 years or over to complete the questionnaire.

What are the benefits/risks?

There are no known potential benefits or risks to participating in this study.

What if I do not want to take part?

Participation in this research study is entirely your choice. Only those people who give their informed consent will be included. If you decide not to participate, your relationship with the University will not be affected in any way.

What if I change my mind during the study?

You may choose not to answer any questions in the questionnaire as you see fit. You may withdraw from the study at any time without giving a reason, and you have the option to withdraw any information you have provided.

What happens to the information?

Information obtained from your participation will be stored anonymously using an identification number and will only be accessed by the researchers involved in the study. Information will be securely stored by the researchers in a locked cabinet or in a computer file accessible only by the researchers. All information resulting from this research will be stored securely by the researchers for a period of seven years, after which it will be destroyed. Individual participants will not be identifiable in any reports or publications arising from the project.

Will there be further studies like this?

Yes. There will be further questionnaire studies over the next 2-3 years to seek users' opinions on the design and marketing of an exoskeleton product. If you would like to be contacted to take part in these studies, please tell the research team and provide contact details. If you express an interest in further participation now and change your mind later, you may withdraw your details at any stage.

If you have further questions regarding this research please feel free to get in touch with either myself or the Principle Investigator using the details listed below.

If you have concerns about this study and wish to contact someone independent, you may contact: The Chair, Faculty of Science & Engineering Research Ethics Committee, University of Limerick, Limerick. Tel: 061 202802

Yours sincerely,

Dr Valerie Power MISCP Post-Doctoral Researcher, Department of Design and Manufacturing Technology, University of Limerick, Ireland E-mail: Valerie.Power@ul.ie	Dr Leonard O'Sullivan FIES, MIEHF, MHFES, MIOSH Principle Investigator, Senior Lecturer Human Factors & Ergonomics, Department of Design and Manufacturing Technology, University of Limerick, Ireland Tel: 00 353 61 234249 E-mail: Leonard.O'Sullivan@ul.ie

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OLLSCOIL LUIMNIGH

CONSENT FORM

I, the undersigned, declare that I am willing to take part in research for the project entitled 'A Questionnaire-Based Study to Determine End User Needs for an Exoskeleton to Assist Older Adults'.

- I declare that I have been fully briefed on the nature of this study and my role in it and have been given the opportunity to ask questions before agreeing to participate.
- The nature of my participation has been explained to me and I have full knowledge of how the information collected will be used.
- I fully understand that there is no obligation on me to participate in this study
- I fully understand that I am free to withdraw my participation at any time without having to explain or give a reason
- I am also entitled to full confidentiality in terms of my participation and personal details

_____

Name (in block capitals)

_____ _____

Signature of participant Date

(Optional) I would like to be contacted about further surveys in relation to this research:

Yes ☐ No ☐

Contact Telephone Number: _____

Email: _____

11. Appendix D: Ireland – 3D Motion Capture Study Ethics Application

Faculty of Science and Engineering Ethics Committee
Expedited Form for
research involving human participants

1: Applicants Details **Form Must Be Typed**

Principal Investigator name: Dr Leonard O'Sullivan Principal Investigator email: Leonard.O'Sullivan@ul.ie
Staff name: Dr Valerie Power
ID number: 1000835TS
Email address: Valerie.Power@ul.ie
Programme of study: Postdoctoral Researcher
FYP, MSc or PhD Dissertation: n/a
Working title of study: 'Biomechanical analysis of human activities of daily living to inform assistive exoskeleton design'
Period for which approval is sought: S**tart Date:** Date of Approval **End date**: Dec2015

2. Human Participants
Does the research proposal involve:

- Working with participants over 65 years of age? Yes☐ No✓☐
- Any person under the age of 18? Yes No✓☐
- Adult patients? Yes☐ No✓☐
- Adults with psychological impairments? Yes☐ No✓☐
- Adults with learning difficulties? Yes☐ No✓☐
- Relatives of ill people (e.g. parents of sick children) Yes No✓
- Adults under the protection/control/influence of others (e.g. in care/prison)? Yes No✓☐☐
- People who may only have a basic knowledge of English? Yes☐ No✓☐
- Hospital or GP patients (or HSE members of staff) recruited in medical facility? Yes☐ No✓☐

3. Subject Matter
Does the research proposal involve:

- Sensitive personal issues? (e.g. suicide, bereavement, gender identity, sexuality, fertility, abortion, gambling)? Yes No✓☐
- Illegal activities, illicit drug taking, substance abuse or the self-reporting of criminal behaviour? Yes☐ No✓☐
- Any act that might diminish self-respect or cause shame, embarrassment or regret? Yes No✓☐
- Research into politically and/or racially/ethnically and/or commercially sensitive areas? Yes No✓☐

4. Procedures
Does the research proposal involve:

- Use of personal records without consent? Yes No✓☐
- Deception of participants? Yes No✓☐
- The offer of large inducements to participate? Yes No✓☐
- Audio or visual recording without consent? Yes No✓☐
- Invasive physical interventions or treatments? Yes No✓☐
- Research that might put researchers or participants at risk? Yes No✓☐
- Storage of results data for less than 7 years? Yes No✓☐

If you have answered **Yes** to any of these questions in sections 2 to 4 above, you will need to fill in the ULREC application form and submit to the Faculty Ethics Committee for review. However, if the research is to be conducted **during teaching practice**, and within the Department of Education subject syllabus outline, and provided the student has the permission of the class teacher and the school principal and that parent/guardians consent to participation, this expedited form can also be used. Please note that if the Faculty Ethics Committee deems it necessary you may be asked to fill in the full application form

Please note that only **1** hard copy of the FREC form is required for the Faculty Ethics Committee. You can get more information and download the forms needed at this address: www.ul.ie/researchethics/
NB: If you answered **Yes** to the last bullet point in section 2 then you will need to apply to the local HSE ethics committee not the FREC.

If you have answered **No** to all of these questions, please answer the following questions in sections 5.

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5 Research Project Information

5a Give a brief description of the research. (Give details of what you and the participant will be doing for this study)

Research Purpose

The proposed study is intended to be carried out as part of the AXO-SUIT project (www.axosuit.eu), which is funded by the European Commission under the Ambient Assisted Living Joint Programme Initiative Call 6. The AXO-SUIT project aims to design, develop, and validate upper-, lower- and full-body assistive exoskeletons for older adults, which comfortably fit the human body and actively help the wearer in their daily activities.

Declining mobility and capacity to perform activities of daily living among ageing adults can lead to loss of independence, decreased engagement in the community and reductions in quality of life (Gill et al. 1995; Gill & Kurland 2003). Exoskeletons have the potential to provide active assistance to augment users' performances of functional activities and thus facilitate maintained independence and social participation (Dollar & Herr 2008).

Research Aims

The aim of the proposed study is to obtain human kinematic and kinetic data for a range of common activities of daily living. This data will be used to drive biomechanical models which will inform the design specifications of the AXO-SUIT upper-body, lower-body and full-body sub-systems.

Procedures

Participants will be recruited via advertisement using the University of Limerick staff/student email system. Eligible participants will be asked to attend a single testing session which is expected to be of 4 hours maximum duration. This session will include a 30-minute break period to allow participants to rest and the Codamotion drive boxes to recharge. At the testing session, participants will first be asked to read the Information Sheet and, if they are willing to participate, sign the Consent Form.

Once consent has been obtained, participants will be asked about their current health status to ensure eligibility to participate, and will have basic information recorded: height, body mass, age and gender. Each participant will then be asked to perform 10 different activities of daily living while kinematic and kinetic data are recorded. These activities have been selected based on preliminary results from a previous questionnaire study carried out as part of the AXO-SUIT project. (Reference No.: 2015_01_07_S&E).

The activities are as follows:

1. Standing
2. Sit to stand/stand to sit from a chair

3. Walking and turning (across an 8 metre walkway)
4. Lifting and lowering a 4kg load from mid-shin height to a table
5. Reaching over head height in front and across the body
6. Pushing and pulling a 2kg load across a table
7. Standing holding a tray weighing 4kg.
8. Getting up from kneeling
9. Getting up from a squatted position
10. Carrying a 0.5kg load in front and to the side of the body in one hand.

Participants will be provided with instructions and a demonstration of how to complete each activity, and will be given a practice trial for each also. Approximately 3 trials will be recorded for each activity of daily living to ensure that optimal Codamotion marker visibility and force plate contact is obtained. Testing will be complete once all activities of daily living have been performed and recorded. At the end of the testing session, participants will be provided with a One-for-All voucher to the value of €50.

Equipment

- Codamotion 3-dimensional motion analysis system: This system will be used to capture 3-dimensional motion data. Active markers – and the drive boxes that power them – will be placed on participants' skin using standard double-sided tape, and secured using hypoallergenic tape or zinc oxide sports tape if necessary. Markers will be placed according to an adapted version of the Plug-In Gait marker configuration, as described in Table 1 below.

Table 1: Codamotion markers and descriptions of locations.

Marker Name	**Marker Location**
Left/Right Shoulder	On the superior aspect of the acromioclavicular joint line
Left/Right Upper Arm	On the upper arm midway between the Shoulder and Elbow markers
Left/Right Elbow	On the lateral epicondyle of the humerus approximating the elbow joint axis
Left/Right Forearm	On the posterior surface of the lower arm midway between the Elbow and Wrist markers
Left/Right Wrist A	On the posterior aspect of the radial styloid process
Left/Right Wrist B	On the posterior aspect of the ulnar styloid process
Left/Right Finger	On the dorsum of the hand just below the head of the 2nd metacarpal
Left/Right ASIS	On the anterior superior iliac spines of the pelvis
Left/Right PSIS	On the posterior superior iliac spines of the pelvis
Left/Right Thigh	On the lateral aspect of the thigh midway between the ASIS and Knee markers
Left/Right Knee	On the lateral femoral epicondyle
Left/Right Ankle	On the lateral malleolus of the fibula
Left/Right Heel	On the posterior aspect of the calcaneus, at the insertion of the Achilles tendon
Left/Right 1st Toe	On the dorsum of the foot at the head of the 1st metatarsal
Left/Right 5th Metatarsal	On the dorsum of the foot at the head of the 5th metatarsal

- AMTI AccuGait portable force plate: This will be used to measure ground reaction forces. The force plate will be embedded into a portable walkway on which the activities will be performed. Participants will be instructed to make contact with it as appropriate to each activity e.g. stand on it during lifting, step on it during walking etc.

5b How many participants will be involved?
10 healthy adults: 5 males and 5 females.

5c How do you plan to gain access to /contact/approach potential participants?
Advertisement via email to all University staff and students (see attached). Since there is a considerable time demand involved, participants will be offered a One-for-All voucher to the value of €50 as an incentive to participate.

5d What are the criteria for including/excluding individuals from the study?

Inclusion criteria:

- Aged 18 to 55 years
- In good physical health

Exclusion criteria:

- Current neurological or musculoskeletal condition or injury which impairs performance of activities of daily living
- Current muscle soreness resulting from vigorous exercise in the previous 48 hours
- Current use of medication which impairs performance of activities of daily living
- Cognitive impairment which limits an individual's capacity to provide informed consent to participate
- Vision and/or hearing impairments which limit an individual's capacity to safely follow instructions and perform the required activities
- Non-English speaking participants, as the information sheet, consent form and instructions to participants will only be available in English

5e Have arrangements been made to accommodate individuals who do not wish to participate in the research? (NB This mainly relates to research taking place in a classroom setting)

Yes **No** **N/A✓**

If Yes
Please state what these arrangements are.

5f Can you identify any particular vulnerability of your participants other than those mentioned in section 2?

No.

5g Where will the study take place? (If in UL please state where)

In UL, in HS2-009 or HS2-005 (depending on the availability of laboratory bookings).

5h What arrangements have you made for anonymity and confidentiality? (How will participants be referenced in the final report)

Each participant's data will be assigned a code, and no identifiable personal details will be stored with this data. Participants' data will only be referred to by the assigned codes in any reports or publications arising from this study to ensure anonymity.

Participants will be asked if they are willing to consent to having their performances of the activities of daily living photographed or recorded, to assist with data analysis and interpretation. Participants may opt out of this aspect of the study, and those who do provide consent will have their faces out of view or obscured in any video/image files that are stored to ensure that anonymity is maintained.

5i What are the safety issues (if any) arising from this study, and how will you deal with them?

Participants may become fatigued during the testing session as there are a number of activities of daily living to be performed. To prevent this, participants will be offered regular short rest periods, as well as a 30-minute break during the testing session.
There is also a minor risk of injury during manual handling activities e.g. lifting. Low loads for manual handling activities, a small number of repetitions and the provision of rest periods for participants will be used to reduce this risk.

5j How do you propose to store the information once the project is completed? Will the file/computer be password protected? (Information must not be stored on student's PC or on a USB Key)

Electronic data will be stored in password-protected files on an external hard drive. No identifiable information will be stored with this data. Consent forms and any hard copy data will be retained in a locked cabinet in the Principle Investigator's office at the University of Limerick. After 7 years, electronic data will be deleted from the hard drive on which it is stored and hard copy data will be shredded.

Where will the information be stored (room number):

F2-022

5k Insurance Cover

Insurance cover is required for all research carried out by UL employees. Principal Investigators/Supervisors should carefully view the University's 'Guidelines on Insurance Cover for Research' document and the University's Insurance cover to ascertain if their proposed research is covered. These documents are available at www.ul.ie/insurance.

Where any query arises about whether or not proposed research is covered by insurance, the Principal Investigator/Supervisor must contact the University's Insurance Administrator at cliona.donnellan@ul.ie to confirm that the required level of insurance cover is in place.

Please indicate by way of signature that the research project is covered by UL's insurance policies:

PI/Supervisor signature: _____

5l Please attach the relevant information documents and complete the following checklist to indicate which documents are included with application

Participant Information Sheet	Yes✓☐	No☐
Participant Informed Consent Form	Yes✓☐	No☐
Parent/Guardian Information Sheet	Yes☐	No✓
Parent/Guardian Informed Consent Form	Yes☐	No✓☐
School Principal Information Sheet	Yes☐	No✓☐
School Principal Informed Consent Form	Yes☐	No✓☐
Teacher Information Sheet	Yes	No✓
Teacher Consent Form	Yes	No✓
Child Protection Form (must be included if dealing with <18 year olds)	Yes	No✓
Questionnaire & Explanatory Cover Letter	Yes☐	No✓☐
Interview/Survey Questions	Yes☐	No✓☐
Recruitment letters/Advertisements/Emails, etc.	Yes✓☐	No☐

6. Declaration

The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

I undertake to abide by the guidelines outlined in the UL Research Ethics Committee guidelines http://www.ul.ie/researchethics/

I undertake to inform S&EEC of any changes to the study from those detailed in this application.

Staff:	**Name: Dr Valerie Power** **Signature:**	**Date:**
Principal Investigator*:	**Name: Dr Leonard O'Sullivan** **Signature:**	**Date:**

* In the case where the principal investigator is not a permanent employee of the University, the relevant head of department must sign this declaration in their place.

You should return this form with signatures to the S&E Ethics Committee c/o Faculty Office, Faculty of Science & Engineering, University of Limerick. In addition, a single pdf file containing the completed form and additional information (e.g. participant information sheet) should be emailed to SciEngEthics@ul.ie This form must be submitted and approval granted before the study begins.

UNIVERSITY of LIMERICK
OLLSCOIL LUIMNIGH

INFORMATION SHEET

'Biomechanical analysis of human activities of daily living to inform assistive exoskeleton design'

You are invited to take part in the research project named above which is being conducted by researchers from the University of Limerick.

What is the study about?
This study aims to find out the human biomechanical characteristics of a selection of common activities of daily living. This information will be used to inform the design of a wearable assistive device for older adults (an "exoskeleton"). In a previous questionnaire study (Reference No.: 2015_01_07_S&E), we asked older adults about the activities of daily living in the home and the community for which they require assistance. In the current study, healthy younger adults will recreate some of the main activities identified. Kinematic and kinetic data will be recorded for these activities, and will be used to determine the design specifications of the exoskeleton.

Who is taking part?
We are seeking 10 people aged 18-55 years: 5 males and 5 females. Participants must be in good physical health, with no current injuries, health conditions or medication usage which impairs performance of activities of daily living.

What do I have to do?
If you decide to participate, you will be asked to:

- Contact the researchers to arrange a testing session at a suitable date and time.
- Attend a single testing session in the Health Sciences Building at the University of Limerick.
- Complete the consent form attached to this information sheet.
- At the testing session, you will be asked to complete the following activities of daily living while 3-dimensional motion data and force plate data are recorded:
    - Standing
    - Standing holding a tray weighing 4kg
    - Reaching upwards, as if opening/closing a curtain
    - Lifting and lowering a 4kg box from mid-shin height to a table
    - Sit to stand/stand to sit from a chair
    - Walking and turning (across an 8 metre walkway)
    - Carrying a 0.5kg load in one hand
    - Pushing and pulling a 2kg load across a table while seated
    - Getting up from kneeling
    - Getting up from a squatted position
- During the testing session you will be asked to wear markers on your body to allow your movements to be recorded and analysed. This will require you to wear either shorts only (males) or shorts and a vest top (males/females).
- Photographs/videos may be taken while you perform these activities to help with later data analysis. If you do not wish to have your performance photographed/recorded, please inform the researchers. You may still participate in the study without having any photographs/videos of your performance taken.

How long will it take?
The testing session is expected to last a maximum of 4 hours.

What are the benefits/risks?
By taking part in this study, you will be contributing to the development of an assistive exoskeleton that aims to improve function, participation and quality of life for older adults. You will also have the opportunity to broaden your knowledge of human movement sciences. All participants will also receive a €50 One-for-All voucher.
There are minimal risks associated with participation in this study. To reduce the risks of discomfort, fatigue or injury during testing, low loads will be used for all manual handling activities and regular rest periods will be provided to you.

What if I do not want to take part?
Participation in this research study is entirely voluntary. Only those people who attend a testing session and give their informed consent will be included.

What if I change my mind during the study?
You may choose to opt out of any aspect of the testing session as you see fit. You may withdraw from the study at any time without giving a reason, and you have the option to withdraw any information you have provided.

What happens to the information?
Information obtained from your participation will be stored anonymously using an identification number and will only be accessed by the researchers involved in the study. Information will be securely stored by the researchers in a locked cabinet or in a password-protected computer file. All information resulting from this research will be stored securely by the researchers for a period of seven years, after which it will be destroyed. Individual participants will not be identifiable in any reports or publications arising from the study.

If you have further questions regarding this research please feel free to get in touch with either myself or the principle investigator using the contact details listed below.

If you have concerns about this study and wish to contact someone independent, you may contact: The Chair, Faculty of Science & Engineering Research Ethics Committee, University of Limerick, Limerick. Tel: 061 202802

Yours sincerely,

Dr Valerie Power Postdoctoral Researcher, Design Factors Research Group, University of Limerick. Valerie.Power@ul.ie	Dr Leonard O'Sullivan Senior Lecturer Human Factors & Ergonomics, Department of Design and Manufacturing Technology, University of Limerick. Tel: 00 353 61 234249 E-mail: Leonard.O'Sullivan@ul.ie

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OLLSCOIL LUIMNIGH

CONSENT FORM

Consent Section:
I, the undersigned, declare that I am willing to take part in research for the project entitled **"Biomechanical analysis of human activities of daily living to inform assistive exoskeleton design"**.

- I declare that I have been fully briefed on the nature of this study and my role in it and have been given the opportunity to ask questions before agreeing to participate.
- The nature of my participation has been explained to me and I have full knowledge of how the information collected will be used.
- I am aware that my participation in this study may be photographed and/or recorded (camera/video) and I agree to this. However, at any time I can request that the recording equipment be switched off. My face will be obscured in any photographs used for illustrative purposes. Any photographs/recordings will be destroyed once the study is completed.

  Consent to photograph/video recording: Yes ☐ No ☐
- I fully understand that there is no obligation on me to participate in this study
- I fully understand that I am free to withdraw my participation at any time without having to explain or give a reason
- I am also entitled to full confidentiality in terms of my participation and personal details

_____ _____

Signature of Participant Date

Research Participants Required

'Biomechanical analysis of human activities of daily living to inform assistive exoskeleton design'

Are you:

- Aged 18 to 55 years?
- Currently in good health and free from injury?

We are currently seeking participants for a study of human movement during common activities of daily living performed in and around the home.

Participants will be required to attend one testing session of 4 hours maximum duration at the University of Limerick. At this session, participants will be asked to perform some common activities e.g. walking, standing up from a chair, carrying objects, bending to pick up items from the floor. A 3-dimensional motion analysis system will be used to capture movement data during these activities. The data will be used to inform the design specifications for an assistive exoskeleton for older adults (www.axo-suit.eu).

All participants will receive a €50 One-for-All voucher.

If you are interested in participating or would like further information about the study, please contact Dr Valerie Power (Valerie.Power@ul.ie).

This research has received approval from the Science and Engineering Research Ethics Committee (2015_05_12). If you have any concerns about this study and want to contact someone independent you may contact:

The Chairperson

Faculty of Science and Engineering Research Ethics Committee

University of Limerick

Tel: 061 202802

12. Appendix E: Sweden – Consent Form

Consent form to participate in lower body mobility exoskeleton systems research

Research at University of Gävle with Gävleborg communities, Gävle, Sweden and European partners
Project leader: Professor Gurvinder S Virk; Email: gurvinder.virk@hig.se; Mob: +46 705 406425, Address: Room 99-423, Kungsbäcksvägen 47, 801 76, Gävle, Sweden
Researchers: Indrawibawa I Nyoman, Usman Haider and others

Short description of the project: The 3-year project which started on 1st Oct. 2012 aims to develop lower-body assistive mobility exoskeletons for helping elderly people move around for active daily living tasks in an independent manner. These motions include performing tasks such as standing up, sitting down, straight walking on flat ground, stable standing, walking over objects, walking on soft ground such as grass, walking up and down ramps, stair climbing/descending, etc. Our work will involve as much input from a variety of end users within our End User Group to carry out the following activities to suit the specific interests of the members:

1. Soliciting individual views and comments for progressing the EXO-LEGS work plan via a variety of method such as, e-methods, responding to questionnaires, commenting on proposals put forward by the project partners, etc.
2. Attendance at EXO-LEGS events to participate in detailed discussions on the EXO-LEGS work plan
3. Participation in experimental studies related to the EXO-LEGS work plan for some volunteers; this will require additional ethical consent consideration and will include wearing an exoskeleton, performing motion tasks and recording of data from the user testing studies.

A range of people from the potential end user population will be included in the research. The inputs made or data collected from volunteers will be analysed and used for the EXO-LEGS and related research activities only and not passed to other organisations. These inputs/data will be used in an anonymous manner and no correlation with specific individuals will be made.

Thank you for agreeing to assist us in our research. Please complete and sign the form to indicate your agreement and confirmation to the following statements:

(i) I confirm that I have been informed about the aims of the planned research and have had the opportunity to ask questions to clarify any issues not clear to me.
(ii) I agree to take part in the planned research and I have been informed that my participation is voluntary and that I am free to withdraw at any time, without giving reason.
(iii) I agree to my inputs to the research project being recorded as appropriate so that the data can be stored and used in the planned research.
(iv) I agree to the use of any quotes I make during the testing but only in an anonymous manner.
(v) I consent to the processing of personal data as described in the information provided.

Name:	Signature:
Address:	Mob:
	Email:

Your name and contact details are only used to administer the end users/volunteers within the research project and will not be used in any other way without your consent. Please provide the following data, which will be the only information used to categorize your involvement in the planned research. Responsible for the processing of personal data is the University of Gävle. According to the Personal Data Act you have the right to once a year be informed about data of you that is being managed and if required have inaccuracies corrected. Contact person for this is Prof. Gurvinder S. Virk. (phone and address is given above).

Gender: Male/ Female Date of birth: ……

Preferred Level of involvement in the End Users Group:

Low: Responses to simple questionnaires (via email) on summary proposals made by the EXO-LEGS team	Medium: Full reports supplied to allow detailed inputs plus follow up e-discussions and meetings	High: Attendance at actual project events for detailed and intensive involvement. Funding is available for this.

☐	☐	☐

Samtycke till deltagande i forskning vid test av exoskelett för nedre delen av kroppen

Forskningsprojekt vid Högskolan i Gävle och Gävleborgs kommuner, Gävle, Sverige.
Projektledare: Professor Gurvinder S Virk; Email: gurvinder.virk@hig.se; Mob: +46 705 406425, mobil: +46 705 406425, adress: rum 99:423, Kungsbäcksvägen 47, 807 76 Gävle, Sverige.
Forskare: Indrawibawa I Nyoman, Usman Haider och andra

Kortfattad projektbeskrivning: 3-årsprojektet som startade 1 oktober 2012 har som mål att utveckla exoskelett för nedre delen av kroppen i syfte att förbättra mobiliteten hos personer och därmed underlätta deras vardagliga uppgifter. Uppgifter som till exempel att stå upp, sätta sig ned, gå rakt på jämn terräng, stå stabilt, kliva över objekt, gå på mjuk terräng så som gräs, gå upp och ned i trappor, etc. Under vårt arbete kommer vi att samla in tillräckligt mycket data från ett stort antal olika slutanvändare/frivilliga inom vår slutanvändargrupp för att kunna anpassa nedanstående aktiviteter till den enskilde personens intresse:

1. Införskaffa enskildas synpunkter och kommentarer för att utveckla arbetet med EXO-LEGS via olika metoder såsom webbaserade metoder, svara på enkäter, kommentera framställda förslag från projektet
2. Deltagande i EXO-LEGS evenemang för att på en djupare detaljnivå kunna medverka i utvecklingsarbetet med EXO-LEGS
3. Deltagande i experimentella studier relaterade till utvecklingsarbetet med EXO-LEGS för några frivilliga. Detta kommer att kräva ytterligare etiskt samtycke och inkluderar att bära ett exoskelett och utföra rörelser. Det innebär också registrering av användardata från dessa tester.

En grupp potentiella slutanvändare kommer att involveras i forskningen. Synpunkter och insamlade data från frivilliga kommer att analyseras men endast för att användas i utvecklingsarbetet med EXO-LEGS . Dessa uppgifter kommer naturligtvis att hanteras konfidentiellt och ingen koppling till specifika individer kommer att kunna göras.

Tack för att du hjälper oss i vår forskning. Vänligen komplettera formuläret nedan och skriv under för att acceptera följande villkor:

(i) Jag bekräftar att jag läst har blivit informerad om syftet med forskningen och har haft tillfälle att ställa frågor för att reda ut oklarheter.
(ii) Jag accepterar att ta del i beskriven forskning och jag har blivit informerad att min insats är helt frivillig och att jag kan avbryta deltagandet närhelst jag vill utan att behöva uppge några skäl eller förklaringar.
(iii) Jag accepterar att min insats inom forskningsprojektet registreras och sparas elektroniskt så att den kan används i den planerade forskningen.
(iv) Jag accepterar att mina uttalande under forskningen får användas, men naturligtvis, under förutsättning att uttalandena har anonymiserats.
(v) Ger sitt tillstånd till behandling av personuppgifter enligt beskrivningen I forskningspersoninformationen.

Namn:	Namnteckning:
Adress:	Mob:
	E-post:

Ditt namn och dina kontaktuppgifter kommer endast att används för att administrera deltagande i forskningsprojektet. Uppgifterna kommer inte att användas på annat sätt utan ditt medgivande. Vänligen fyll i följande uppgifter vilka kommer att vara den enda information som används för att kategorisera ditt deltagande i den planerade forskningen. Personuppgiftsansvarig är Högskolan i Gävle. Enligt personuppgiftslagen (PuL) har du rätt att gratis en gång per år få ta del av de uppgifter om Dig som hanteras och vid behov få eventuella fel rättade. Kontaktperson är Prof. Gurvinder S. Virk (telefonnummer och adress anges ovan).

Kön: Man/ Kvinna Födelsedatum:……

Önskad nivå för deltagande i slutanvändargruppen

Låg: Besvara enkla frågeformulär på summariska förslag från EXO-LEGS (via e-post)	Medium: Tillgång till *fullständiga* rapporter och möjlighet att göra detaljerade kommentarer samt uppföljning via möten	Hög: Deltagande i EXO-LEGS evenemang vilket kräver större engagemang. Finansiering finns för detta
☐	☐	☐

13. Appendix F: Belgium – Request for Approval from Ethical Committee

ETHISCH COMITE
Universitair Ziekenhuis
De Pintelaan 185
9000 Gent
ethisch.comite@UGent.be
tel. +32 9 332 33 36 - +32 9 332 68 54 - +32 9 332 26 88
fax +32 9 332 49 62

:zoek)

VERZOEK TOT ADVIES VAN HET ETHISCH COMITE BETREFFENDE EEN ONDERZOEKSPROJECT BIJ DE MENS

EUDRACT NUMMER (INDIEN INTERVENTIONEEL GENEESMIDDELENONDERZOEK):

1. TITEL VAN HET ONDERZOEK :

AXO-SUIT EXOSKELETON EINDGEBRUIKERS BEVRAGING

2. GEGEVENS VAN DE ONDERZOEKER(S) [de eerste onderzoeker moet een persoon zijn die vast verbonden is aan de dienst (geen ASO) of universiteit] :

- NAAM: PROF DR KRISTL VONCK
- FUNCTIE: ZAP
- UZ DIENST : NEUROLOGIE, INWENDIGE GENEESKUNDE GE01
  OF FACULTEIT/VAKGROEP:
- TELEFOONNUMMER: 09 332 45 39
- FAX: 09 332 38 62
- E-MAIL: KRISTL.VONCK@UGENT.BE
- NAAM UZ DIENSTHOOFD: PROF DR PAUL BOON
  OF NAAM VAKGROEPVOORZITTER:

3. GEGEVENS VAN DE MEDEWERKER(S) AAN DE STUDIE:

- NAAM: STEFANIE GADEYNE
- FUNCTIE:
- UZ DIENST : NEUROLOGIE, INWENDIGE GENEESKUNDE GE01
  OF FACULTEIT/VAKGROEP:
- TELEFOONNUMMER: 09 332 10 50
- FAX: 09 332 57 09
- E-MAIL: STEFANIE.GADEYNE@UGENT.BE
- NAAM UZ DIENSTHOOFD: DR PAUL BOON
  OF NAAM VAKGROEPVOORZITTER

- CATHY NAUDTS
- MILITZA BVBA
- GROENVINKSTRAAT 2/444, 9041 OOSTAKKER
- TELEFOONNUMMER:
- E-MAIL:

4. SOORT ONDERZOEK:

☒ NIET-INTERVENTIONEEL ONDERZOEK

☐ RETROSPECTIEF

☒ BEVRAGING (VRAGENLIJST, INTERVIEW)

☐ ANDERE, SPECIFICEER:

☐ INTERVENTIONEEL ONDERZOEK

☐ MET GENEESMIDDEL (ALLE ITEMS VAN TOEPASSING AANDUIDEN)
- ☐ FASE I
- ☐ FASE II
- ☐ FASE III
- ☐ FASE IV
- ☐ PROEF VOOR GENTHERAPIE EN SOMATISCHE CELTHERAPIE
- ☐ PROEF MET GENEESMIDDELEN DIE GENETISCH GEWIJZIGDE ORGANISMEN BEVATTEN
- ☐ PROEF MET CELTHERAPIE MET XENOGENEN

☐ ANDERE SPECIFICEER (VB MEDICAL DEVICE**,** BLOEDAFNAME, RX,…)
- ☐ MEDICAL DEVICE
- ☐ BLOEDAFNAME, RX,…
- ☐ VRAGENLIJSTEN, INTERVIEW, ENQUETE,…

5. IS HET ONDERZOEK

☐ DIAGNOSTISCH	☐ THERAPEUTISCH
☐ FYSIOLOGISCH	☐ FYSIOPATHOLOGISCH
☒ MORFOLOGISCH	☐ EPIDEMIOLOGISCH

6. IS HET ONDERZOEK IN BELGIË

☐ MONOCENTRISCH

☒ MULTICENTRISCH

☒ HET ETHISCH COMITÉ UZ GENT IS "CENTRAAL" ETHISCH COMITÉ

☒ JA

- NAAM, ADRES, TEL. ,FAX EN E-MAIL VAN ANDERE ETHISCHE COMITÉ DIE MEEWERKEN AAN HET ONDERZOEK + NAAM VAN LOKALE ONDERZOEKER

☐ NEEN

- NAAM, ADRES, TEL, FAX EN E-MAIL VAN HET CENTRAAL ETHISCH COMITÉ

7. OPDRACHTGEVER VAN DE GESPONSORDE STUDIE

☐ FARMACEUTISCHE FIRMA (NAAM EN ADRES):

☒ ANDERE, SPECIFIEER (NAAM EN ADRES):

COMMETO BVBA
VELDHOVENSTRAAT 40
3945 HAM

PARTNER IN HET EU AAL PROJECT AXO-SUIT IN COOPERATIE MET DE UNIVERSITEIT VAN GÄVLE,

UNIVERSITEIT VAN AALBORG EN UNIVERSITEIT VAN LIMERICK.
ZIE OOK HTTP://WWW.AXO-SUIT.EU/

8. GEEF EEN KORTE SAMENVATTING VAN HET PROTOCOL (MINIMUM 30 ZINNEN / EEN HALVE PAGINA EN MAXIMUM ÉÉN PAGINA), VERSTAANBAAR VOOR MENSEN NIET GESPECIALISEERD IN DE MATERIE, VERWIJS NIET ALLEEN NAAR EEN BIJGEVOEGD PROTOCOL.

ONDERZOEK VIA BEVRAGING VAN HET DOELPUBLIEK NAAR DE PRECIEZE NODEN VAN PATIËNTEN VOOR DE ONTWIKKELING VAN EEN MODULAIR, ASSISTIEF EXOSKELETON. DIT EXOSKELETON HEEFT TOT DOEL DE KRACHT VAN LICHT MOTORISCH GEHANDICAPTE PERSONEN EN PERSONEN VAN DE DERDE LEEFTIJD TE SUPPLEMENTEREN MET TOT DOEL HEN EEN GROTERE AUTONOMIE TE BEZORGEN. HET EXOSKELETON ONDERSTEUNT DE FUNCTIE VAN BENEN, ARMEN EN/OF HANDEN.
BEVRAGING VIA BIJGEVOEGDE VRAGENLIJST VAN EEN 40-TAL PERSONEN IN VLAANDEREN.
GESELECTEERDE PERSONEN, M/V, ZIJN WILSBEKWAME VOLWASSENEN VAN MINSTENS 55 JAAR MET EVENTUEEL EEN LICHTE MOTORISCHE HANDICAP. PATIËNTEN ZIJN ENERZIJDS GESELECTEERD DOOR DE BEHANDELENDE ARTS VAN UZ GENT DIENST EUROLOGIE OF ZIJN INWONER VAN HET RUSTHUIS MILITZA TE OOSTAKKER DIE OOK DEELNEEMT AAN HET ONDERZOEK.
HET BETREFT EEN ÉÉNMALIGE BEVRAGING MET ANONIMISATIE DOOR CODERING.
DE GEANONIMISEERDE RESULTATEN VAN HET ONDERZOEK WORDEN VERWERKT DOOR DE UNIVERSITEIT VAN GÄVLE (PROF GURVINDER VIRK).

9. WELKE ZIJN DE ARGUMENTEN (THEORETISCHE, EXPERIMENTELE OF ANDERE) DIE EEN VOORDEEL LATEN VERWACHTEN VAN DE TE TESTEN NIEUWE METHODE, VAN HET TE TESTEN NIEUWE PREPARAAT, ETC. BOVEN DE GEKENDE EN REEDS GEBRUIKTE ?

N.V.T.

10. WERD EEN ANALOOG ONDERZOEK REEDS ELDERS UITGEVOERD, HETZIJ IN ZIJN GEHEEL, HETZIJ GEDEELTELIJK ?

ZO JA, WAAR ? WAT WAS HET RESULTAAT ? WAAROM WORDT HET IN DEZE STUDIE HERNOMEN ?

ONDERZOEK NAAR DE NODEN VOOR EEN "LOWER BODY EXOSKELETON" BINNEN HET EU AAL PROJECT EXO-LEGS DOOR UNIVERSITEIT VAN GÄVLE (ZWEDEN).
HET RESULTAAT LIET TOE HET EXOSKELETON VOOR HET ONDERLICHAAM TE ONTWERPEN VOLGENS DE NODEN VAN DE POTENTIËLE PATIËNTEN.
STUDIE WORDT HERNOMEN OMDAT HET HIER EEN BELANGRIJKE UITBREIDING BETREFT VAN DE BESTAANDE OPLOSSING DIE NU OOK BOVENLICHAAM EN HANDEN OMVAT ALSOOK EEN BELANGRIJKE VORM VAN MODULARITEIT ZAL INHOUDEN.

11. ZAL EEN CHEMISCHE SUBSTANTIE TOEGEDIEND WORDEN ?

☐ JA ☒ NEEN

ZO JA:

A. LANGS WELKE WEG ?

B. NAAM EN OORSPRONG VAN DE SUBSTANTIE :

C. AAN WIE WORDT DE RECEPTIE, OPSLAG, VERDELING EN TERUGSTUREN VAN NIET-GEBRUIKTE CHEMISCHE SUBSTANTIES TOEVERTROUWD ?

D. ZULLEN RADIO-ISOTOPEN TOEGEDIEND WORDEN ?

☐ JA ☒ NEEN

WELKE ?

12. INDIEN HET OM EEN NIEUWE SUBSTANTIE GAAT, HEEFT DE ONDERZOEKER KENNIS GENOMEN VAN HET VOLLEDIG TOXICOLOGISCH, DIERFARMACOLOGISCH EN HUMAAN DOSSIER?

☐ JA ☐ NEEN

ZO NEEN, LEG UIT :

13. KEUZE VAN DE PROEFPERSONEN :

A. GEZONDEN ?

☒ JA ☒ NEEN

PATIËNTEN LIJDEND AAN : LICHTE MOTORISCHE BEPERKING

B. ZWANGERE VROUWEN OF VROUWEN DIE TIJDENS HET ONDERZOEK ZWANGER KUNNEN WORDEN ?

☐ JA ☒ NEEN

C. AANTAL PROEFPERSONEN IN HET UZ: 20

D. TOTAAL AANTAL PROEFPERSONEN IN DE STUDIE: 40

E. LEEFTIJD : >55

F. GESLACHT : M/V

G. HOE WORDEN ZE GEREKRUTEERD?

DIENST NEUROLOGIE DOOR BEHANDELENDE ARTS.
RUSTHUIS MILITZA DOOR CATHY NAUDTS.

14. WANNEER VERWACHT MEN VOORDEEL VOOR DE DEELNEMER

A. HEEFT HET EXPERIMENT EEN DIAGNOSTISCH OF THERAPEUTISCH DOEL DAT ONMIDDELLIJK VOORDEEL AAN DE ONDERZOCHTE ZAL BRENGEN ?

☐ JA ☒ NEEN

B. MAAKT HET EXPERIMENT DEEL UIT VAN EEN DIAGNOSTISCH EN THERAPEUTISCH PLAN WAARVAN MEN MAG VERWACHTEN DAT DE RESULTATEN BINNEN AFZIENBARE TIJD VOOR ANDERE ZIEKEN NUTTIG ZULLEN ZIJN ?

☒ JA ☐ NEEN

C. MAAKT HET EXPERIMENT DEEL UIT VAN EEN GEHEEL VAN ONDERZOEKEN WAARVAN HET DIAGNOSTISCH OF THERAPEUTISCH BELANG NIET ONMIDDELLIJK DUIDELIJK IS, MAAR WAARVAN MAG WORDEN VERWACHT DAT DE RESULTATEN LATER TOT DIAGNOSTISCHE OF THERAPEUTISCHE TOEPASSINGEN OF TOT EEN BETERE KENNIS VAN DE FYSIOPATHOLOGISCHE MECHANISMEN ZULLEN LEIDEN ?

☐ JA ☒ NEEN

15. WELKE INVESTIGATIES ZIJN EXTRA VOORZIEN GEDURENDE HET ONDERZOEK, HOE FREQUENT EN GEDURENDE WELKE TIJD ?

A. ZUIVER KLINISCHE EVALUATIES, OM DE .....

B. FUNCTIETESTS OF DYNAMISCHE PROEVEN

WELKE .....

OM DE .....

C. RADIOGRAFISCHE EN/OF ISOTOPISCHE INVESTIGATIES

WELKE .....

OM DE .....

D. BLOEDAFNAMEN : .....

.....

.....

E. WEEFSELAFNAME : .....

F. ANDERE : .....

16. REKENING HOUDEND MET DE HUIDIGE GEGEVENS VAN DE WETENSCHAP:

A. MEENT U DAT DEZE STUDIE:

☒ WAARSCHIJNLIJK GEEN ENKEL RISICO INHOUDT

☐ EEN MOGELIJK RISICO INHOUDT.

WELK, FREQUENTIE :

☐ ZEER WAARSCHIJNLIJK EEN RISICO INHOUDT.

WELK, FREQUENTIE :

B. WELKE ZIJN DE MEEST VOORKOMENDE BIJWERKINGEN VAN HET PREPARAAT ONDER STUDIE ?
(DE BIJWERKINGEN MOETEN EVENEENS DUIDELIJK VERMELD WORDEN IN HET INFORMATIE- EN TOESTEMMINGSFORMULIER VOOR DE DEELNEMER)

N.V.T.

17. INFORMATIE EN TOESTEMMING VAN DE PROEFPERSONEN

A. WILSBEKWAME VOLWASSENEN

☒ JA ☐ NEEN

WORDT DE TOESTEMMING VAN DE PROEFPERSONEN BEKOMEN NA EEN KLARE EN OBJECTIEVE UITEENZETTING VAN HET DOEL VAN HET ONDERZOEK ?

SCHRIFTELIJK :

☒ JA ☐ NEEN

MONDELING :

☒ JA ☐ NEEN

ZO NEEN, WAAROM NIET ?

WORDT IN DIT LAATSTE GEVAL DE TOESTEMMING GEGEVEN DOOR ANDEREN DAN DE PROEFPERSONEN ?

☐ JA ☐ NEEN

ZO JA, DOOR WIE ?

ZIJN ER SPECIALE GROEPEN : EIGEN STUDENTEN, EIGEN PERSONEEL ?

B. WILSONBEKWAME VOLWASSENEN (= SOMMIGE PSYCHIATRISCHE PATIENTEN, PERSONEN IN DE ONMOGELIJKHEID HUN WIL TE UITEN, ...)

☐ JA ☒ NEEN

WORDT DE TOESTEMMING GEGEVEN DOOR ANDEREN DAN DE PROEFPERSONEN ?

☐ JA ☐ NEEN

ZO JA, DOOR WIE ?

C. KINDEREN

☐ JA ☒ NEEN

WORDT DE TOESTEMMING GEVRAAGD VAN HUN WETTELIJKE VERANTWOORDELIJKEN ?

☐ JA ☐ NEEN

IS ER EEN INFORMATIE- EN TOESTEMMINGSFORMULIER VOOR KINDEREN VANAF 12 JAAR VOORZIEN?

☐ JA ☐ NEEN

18. IS HET INFORMATIEFORMULIER VOOR DE PROEFPERSONEN IN BIJLAGE GEVOEGD

☒ JA ☐ NEEN

ZO NEEN, WAAROM NIET ?

19. IS HET FORMULIER VOOR SCHRIFTELIJKE TOESTEMMING IN BIJLAGE GEVOEGD ?

☒ JA ☐ NEEN

ZO NEEN, WAAROM NIET ?

20. ZULLEN DE PERSONEN IN DE LOOP VAN DEZE STUDIE VOORTDUREND ONDER MEDISCH TOEZICHT STAAN

☒ JA ☐ NEEN

A. WIE IS DE TOEZICHTHOUDENDE GENEESHEER ?
PROF DR KRISTL VONCK, UZ GENT DIENST NEUROLOGIE.

B. ZAL DIT TOEZICHT, ZO NODIG, VERZEKERD KUNNEN WORDEN TIJDENS DE UREN DIE OP DE STUDIE VOLGEN ?

☒ JA ☐ NEEN

C. ALS DE PERSOON NAAR HUIS TERUGKEERT TIJDENS DE UREN DIE OP HET ONDERZOEK VOLGEN, ZAL IN GEVAL VAN NOOD SNEL CONTACT MET EEN GENEESHEER KUNNEN OPGENOMEN WORDEN ?

☒ JA ☐ NEEN

D. NAAM VAN DEZE GENEESHEER ?
NEUROLOOG VAN WACHT.

21. IS ER VOOR HET ONDERZOEK EEN VERZEKERING AFGESLOTEN CONFORM DE BELGISCHE WET VAN 7 MEI 2004?(HET VERZEKERINGSCERTIFICAAT MOET BIJ DE AANVRAAG GEVOEGD WORDEN)

☒ JA

A. DOOR WELKE VERZEKERINGSPOLIS BENT U VERZEKERD ?
(VERWIJZEN NAAR EEN BIJGEVOEGD DOCUMENT VOLSTAAT NIET)

➔ COMMETO: A.G. INSURANCE POLIS "99092268 COMMETO"
➔ VIA KBC INSURANCE SOLUTIONS, GELDENAAKSEBAAN 470 , 3001 HEVERLEE, BELGIË.

B. WAT IS DE OMVANG VAN DE DEKKING DOOR DE VERZEKERINGSMAATSCHAPPIJ ?

-> COMMETO

☐ NEEN, WAAROM NIET?

22. FINANCIËLE OVEREENKOMST

(INDIEN EEN DEFINITIEVE FINANCIËLE OVEREENKOMST NOG NIET BESCHIKBAAR IS, DAN KAN EEN BUDGET PROPOSAL DAT TEGENGETEKEND IS DOOR EEN VERTEGENWOORDIGER VAN DE OPDRACHTGEVER VOLSTAAN).(INDIEN HET BEDRAG VAN DE DEFINITIEVE FINANCIËLE OVEREENKOMST HOGER IS DAN HET INGEDIENDE "BUDGET PROPOSAL", MOET DEZE DEFINITIEVE FINANCIËLE OVEREENKOMST ALSNOG TER GOEDKEURING VOORGELEGD WORDEN AAN HET ETHISCH COMITÉ)

☒ NIET VAN TOEPASSING

☐ AANWEZIG MET VOLGENDE ONDERVERDELING:

☐ ERELOON:

☐ VERGOEDING VOOR TECHNISCHE PRESTATIES:

23. BIJ EEN INDUSTRIEGESPONSORDE STUDIE DIENT ER EEN "HANDLING FEE" BETAALD TE WORDEN, DIT NA ONTVANGST VAN DE FACTUUR.

☒ NAAM EN ADRES WAAR FACTUUR DIENT GESTUURD TE WORDEN:

COMMETO BVBA
VELDHOVENSTRAAT 40
3945 HAM

☒ BTW NUMMER:

BE 0474.291.990

IK VERKLAAR DE GEHELE VERANTWOORDELIJKHEID VAN HET HIERBOVEN VERMELD PROJECT OP MIJ TE NEMEN EN BEVESTIG DAT VOOR ZOVER DE HUIDIGE KENNIS HET TOELAAT, DE GEGEVEN INLICHTINGEN MET DE WERKELIJKHEID OVEREENSTEMMEN.

DE ONDERZOEKER,	HET U.Z. DIENSTHOOFD OF DE VAKGROEPVOORZITTER (VOOR AKKOORD)
DATUM :	DATUM :
NAAM :	NAAM :
HANDTEKENING :	HANDTEKENING :

HET UZ-DIENSTHOOFD OF DE VAKGROEPVOORZITTER VAN EVENTUELE ANDERE BETROKKEN DIENSTEN (VOOR AKKOORD)

DATUM :	DATUM :
NAAM :	NAAM :
HANDTEKENING :	HANDTEKENING :

OBSERVATIONAL STUDY AGREEMENT

Study name: AXO-SUIT
Protocol code: XXX
Centre N°: XXX
Principal Investigator: Prof Dr Kristl Vonck

UZ Gent Reference: KW/XXXX/XXX/XXX/XXX

This OBSERVATIONAL STUDY agreement is made between

COMmeto bvba
Veldhovenstraat 40 3945 HAM
VAT BE 0474.291.990
Duly represented by Ludo Cuypers

(Hereinafter referred to as « Sponsor »)

AND

Universitair Ziekenhuis Gent
De Pintelaan 185
9000 Gent

VAT BE 0232.987.862

Duly represented by Prof. dr. E. Mortier, CEO

(Hereinafter referred to as « the Centre»)

AND

Title + Name:	Prof Dr Kristl Vonck, PI
Service:	Department of Neurology
Street:	De Pintelaan 185
City:	Gent

AND

Title + Name:	Prof Dr Paul Boon, Head of Department
Service:	Department of Neurology
Street:	De Pintelaan 185
City:	Gent

The study will take place at the Department of Neurology of the Centre with Prof. Dr. Paul Boon as Head of Department and Prof Dr Kristl Vonck as Principal Investigator.

(Hereinafter referred to as « the Principal Investigator »)

WHEREAS

- Sponsor is engaged in the research, development, manufacture and marketing of the AXO-SUIT exoskeleton for use in human beings; and

- The Principal Investigator is engaged in and has experience in daily medical practice as a health care professional, is willing to co-operate with Sponsor in this Observational Study; and

- Sponsor wishes to call on the support of the Investigator for the elaboration of this observational Study; and

- Each party considers a co-operation in their mutual interest;

THEREFORE IN CONSIDERATION OF THE FOREGOING THE PARTIES AGREE AS FOLLOWS:

1. The Principal Investigator hereby agrees:
   1.1. To carry out on behalf of Sponsor the Observational Study more particularly described in APPENDIX I.
   1.2. To conduct the Observational Study in accordance with the Observational Study Protocol referred to in APPENDIX I and with the Sponsor standard conditions for observational studies referred to in APPENDIX IV.
   1.3. To use all reasonable endeavours to adhere to the timetable set out in APPENDIX I; to report any delays promptly to Sponsor ; and to use all reasonable efforts to recoup time lost thereby.

2. Term of this Agreement
   2.1. This Agreement shall be effective as of date on which both parties agree on the Terms of this Agreement or on the date on which Sponsor shall have obtained all and any necessary approval for the performance of the Study from the competent authorities, whichever occurs last and shall expire upon receipt and acceptance by Sponsor of the work product specified in the Protocol.
   2.2. The following provisions shall survive the termination or expiry of this Agreement: Articles 3.11. (Confidentiality), 3.13 (Publication) and 3.14 (Intellectual Property) of Appendix IV, as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement.

3. In consideration of the services to be provided by the Principal Investigator, Sponsor hereby agrees to make the payments specified in APPENDIX II at the times and in the manner there set out.

4. If needed in order to perform the services to be provided by the Participant, Sponsor hereby agrees to make the equipment or Personnel Related Services specified in APPENDIX III available at the conditions there set out.

5. Each party agrees to observe the principles of Good Clinical Practice applicable in the country or countries where the Clinical Study is to be conducted and to abide by the Declaration of Helsinki and all relevant national or international laws, regulations or guidelines including, without limitation, the law of 7 May 2004 concerning experiments on the human person and the provisions of the Belgian Law of 8 December 1992 on Privacy Protection in relation to the Processing of Personal Data. The Centre and Principal Investigator warrant that the Centre's employees and collaborators involved in the Study will comply with these principles, laws and regulations.

6. Sponsor's Standard Conditions for Observational Studies (see Appendix IV) shall apply to this Agreement as though set out in full, except to the extent that they are modified hereby or by any Appendix hereto.

7. The Principal Investigator agrees to report Adverse Event, both serious and non-serious (SAE and AE), as well as occurrence of pregnancy to the local Sponsor Safety Desk (as described in Appendix IV) and provide follow-up information where necessary.

8. The validity, interpretation and performance of this agreement shall be governed and construed in accordance with the laws of Belgium. For any legal action arising from or related to this agreement, the parties hereby consent and submit solely to jurisdiction and venue of the courts located at Ghent and agree that such courts shall be the sole courts utilized and herby waive any jurisdictional or venue objections to such court.

9. Notices : Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile with confirmation of receipt to the address given in this Agreement or to such other address as may have notified to the other party in writing.

10. Severability : The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

11. Waiver : No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

12. Entire Agreement : This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter here of. An amendment will be made if any change of the details mentioned in the Agreement occurred. No amendment to this Agreement will be effective or binding unless it is in writing signed by each party and refers to this Agreement.

13. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Trial and the treatment of Subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail.

This contract will be executed in three (3) originals, and one (1) will be returned to Sponsor.

The contract is valid if signed below by all parties. Such signature implies approval of the above mentioned information, and of appendixes I, II, III and IV of the Clinical Trial Agreement.

SIGNED on behalf of Sponsor:

Date: _____

Name: Ludo Cuypers
Title: Zaakvoerder

SIGNED on behalf of the Centre:

Date: _____

Name: Prof. dr. E. Mortier
Title: CEO

SIGNED on behalf of the Principal Investigator:

Date: _____

Name: Prof Dr Kristl Vonck
Title: Principal Investigator

SIGNED on behalf of the Head of Department:

Date: _____

Name: Prof. Dr. Paul Boon
Title: Head of Department

APPENDIX I

STUDY SPECIFICATIONS

Study name:	AXO-SUIT
Protocol code:	XXX
Protocol title:	XXX
Protocol date:	11.4.2015
Centre N°:	XXX
Eudract N° :	NA
Principal Investigator:	Prof Dr Kristl Vonck
Company Address: • 013677514 • Fax: 013677520	Veldhovenstraat 40, 3945 Ham
Telephone N°:	+32 13 67 75 14
Fax n°:	+32 13 67 75 20

Start date of study (First Patient First Visit): 01/11/2015

End date of inclusion period (Global Last Patient First Visit): 01/03/2016

End date of study (Global Last Patient Last Visit): 01/04/2016

Total patients foreseen for this centre: 40

APPENDIX II

REMUNERATION

Fee

XXX

Modality of payment

XXX

The payments will be made to:

The parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee:

Name of account holder:	Universitair Ziekenhuis Gent
Address of account holder:	De Pintelaan 185, 9000 Gent
VAT number	BE 0232.987.862
Name bank:	BNP Paribas - Fortis
Bank address:	Ravensteinstraat 29, 1000 Brussel
Bank account number:	001 6448247 54
IBAN:	BE42 0016 4482 4754
Swiftcode:	GEBABEBB
Reference:	**KW/XXXX/XXX/XXX/XXX**

Payments will be payable after receipt of an invoice under the regular VAT regime.

APPENDIX III

STUDY EQUIPMENT – If Applicable

APPENDIX IV

SPONSOR STANDARD CONDITIONS FOR OBSERVATIONAL STUDIES

1. INTRODUCTION

Subject only to any overriding local laws, these Conditions shall apply to all observational studies conducted under the sponsorship of Sponsor whether directly or through a Contract Research Organisation, herefor mandated by Sponsor and shall be deemed to be incorporated in any Agreement relating to any such observational study unless otherwise agreed by Sponsor in writing. If in these conditions, mention is made of Sponsor, Sponsor or a Contract Research Organisation is meant at all times.

Expressions used in these Conditions and in any Agreement relating to a observational study shall be defined in accordance with Article 7 hereof.

2. DUTIES OF Sponsor

2.1 Pre-Study Data

Sponsor will inform the Principal Investigator, prior to the commencement of the Study of all relevant chemical, pharmacological, toxicological and clinical information required for the proper planning and conduct of the Trial and will update this as often as may be necessary during the course of the Study. However, this obligation shall not require Sponsor to provide information which is already readily available in published material or of which the Principal Investigator could reasonably be expected to have knowledge in view of his or her professional training.

1.2. Other Information

Should any relevant information (e.g. any information modifying the risk/benefit assessment of the drug) come to Sponsor's attention during the course of the Study, it will promptly communicate the same to the Principal Investigator.
Sponsor will report adverse drug experiences to the Regulatory Agency, and, together with the Principal Investigator, will take such measures as may be required to protect subjects at risk.

1.3. Study Materials *(If applicable)*

As a prerequisite of the nature of an observational study, no free samples of Study Materials will be used by the Participant.

1.4. Monitoring

Sponsor will nominate a suitably trained person or persons to monitor or supervise the conduct of the Study and to liaise with the Principal Investigator. All such persons nominated by Sponsor will be bound by contractual obligations of confidentiality.

1.5. Reports

On conclusion of the Study Sponsor will supply to the Principal Investigator in confidence a copy of any formal report prepared by it in which the results of the Study and the observational conclusions drawn from it are set out.

1.6. Liability and Insurance

Pursuant to art. 29 of the Belgian law of May 7, 2004 concerning the experiments on the human person :

- Sponsor is liable, even without fault, for the damage that the Study Subject or his legal successors have sustained and that has a direct or indirect link with the Study; and
- Sponsor is required to contract prior to the observational study an insurance covering this responsibility, like that for all intervening parties in the observational study (such as, but not limited

to, the Principal Investigator, any member of the Principal Investigator's staff, the organisation responsible for the Centre and its employees or agents, the pharmacy, the laboratory and the CRO, if any) independent of the nature of bonds existing between the intervening party, the sponsor and the Study Subject.

Sponsor will secure and maintain insurance coverage for product liability of all products involved in this study according to the law of 25 February 1991 concerning the product liability.

3. DUTIES OF THE PRINCIPAL INVESTIGATOR

3.1. Study Protocol

The Protocol, including any amendments, constitutes an integral part of this Agreement and shall be valid only upon signature of this Agreement. In case of any inconsistency between this Agreement and the Protocol, this Agreement shall prevail. For the avoidance of doubt, if any obligation is specified in one of these documents but not in the other, this shall not constitute an inconsistency.

The Principal Investigator will notify Sponsor in advance of any intention to depart from the Observational study Protocol, even in those cases where such departure is unavoidable. Additionally, the Principal Investigator will promptly report any departures from or violations of the Observational study Protocol to Sponsor and if appropriate, to the Ethics Committee.

3.2. Taxes and Social Security Contributions

It shall be the Centre's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Centre and its employees and/or collaborators. Payments related to the Observational Study are subjected to VAT further to circular ET 116.111. Centre / Investigator will specify the choice of VAT regime in appendix II.

3.3. Approvals

The Study shall not commence until:

(a) all the necessary approvals of the ethics committee, as foreseen in the Law of May 7, 2004 concerning the experiments on the human person, have been obtained in writing.

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Centre.

3.4. Centres

The Trial will be conducted only at the Centre or Centres referred to in the Study Agreement unless Sponsor agrees in writing to other Centres being used.

Sponsor shall be permitted to inspect any proposed Centre prior to commencement and during the course of the Study to satisfy itself that the Centre is suitable and has the necessary facilities and staff for the conduct of the Study.

If the Study cannot be conducted by the Principal Investigator alone, the Principal Investigator will:

1.1 recruit adequate numbers of co-investigators having appropriate qualifications and experience to enable it to be carried out in a proper manner and in due time;

2.1 prior to the commencement of the Trial supply to Sponsor a list of the co- investigators proposed to be used together with details of their qualifications and experience, and will not use any co-investigator to whom Sponsor shall raise any objection;

3.1 not supply any Trial Materials to any co-investigator unless and until Sponsor shall have approved the appointment of such co-investigator in writing.

The Principal Investigator will ensure that each Centre has the necessary facilities and staff for the conduct of the Study, and that these will be maintained for the duration of the Study, and will certify to that effect.

The Principal Investigator will ensure that the executive management of the Centres have agreed with the conduct of the Study on their site prior to the start of the Study.

3.5. Assignment

Neither party shall assign this Agreement to any third party without the other party's prior written consent, except that Sponsor shall be entitled to assign this Agreement to any affiliate or to any party which takes over all or substantially all of Sponsor's business.

3.6. Subcontracting

The Centre shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Sponsor. Any such consent shall not relieve the Centre of its obligations hereunder.

3.7. Adverse drug experiences and pregnancies

The Principal Investigator will report to Sponsor within 24 hours any adverse drug experiences occurring during the Study and will co-operate with Sponsor in connection with the reporting of adverse experiences (AE and SAE) to the Health Authjorities and to the Ethics Committee as required by the local country and EU regulations . The same will be done for pregnancies.

The Principal Investigator will take all reasonable measures, in consultation with Sponsor, to protect subjects at risk following the occurrence of a serious adverse drug experience.

3.8. Information

The Principal Investigator will communicate to Sponsor and to the Ethics Committee any relevant information (as described in paragraph 2 of Section II above) coming to his or her attention during the course of the Study.

3.9. Co-operation with CRO, Monitors

The Principal Investigator will co-operate with Sponsor, and any person nominated by Sponsor or any CRO to monitor or supervise the conduct of the Study. In particular, the Principal Investigator will arrange or provide access for any such person to any Centre at which the Study is being conducted and to any records kept for the purposes of the Study, and so far as he is legally permitted to do so and has been authorized by the patients through the informed consent form, to any records relating to the subject for the purpose of verifying the Study records.

3.10. Reports/Records

The Principal Investigator warrants that all (e)CRFs submitted to Sponsor are true, complete and correct and accurately reflect the results of the Study with respect to each person participating as a subject ("Subject").

All (e)CRFs shall be in the form specified by Sponsor for the purposes of the Study and the Principal Investigator will ensure that they are properly completed in accordance with the Study Protocol.
Unless otherwise agreed, all written reports required to be submitted to Sponsor by the Principal Investigator shall be in such form as shall be specified by Sponsor.

In case study documents are provided by the Principal Investigator to Sponsor, all patients should be identified by a study number only. Any further identification (e.g. initials, full name, address) should be deleted. Signed informed consent forms will remain in the study centre. The Principal Investigator will

only include medical data from patients who have been informed about and agreed to the use of their private medical data for the purpose of the Study.

The Principal Investigator will keep for a period of 20 years, or such other period as shall be mutually agreed, a complete set of medical records relating to the subjects, and will produce them or supply copies thereof to Sponsor or to the Regulatory Agency on demand, subject confidentiality being assured so far as practicable.

3.11. Confidentiality

All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Sponsor websites) disclosed to or collected or developed by the Centre, the Principal Investigator and/or the Centre's employees and/or collaborators in connection with this Agreement or the Study (collectively "Confidential Information") shall be treated as confidential. The Centre agrees not to disclose to any third parties or to use any Confidential Information for any purpose other than the performance of the Study. The Centre shall ensure that the Principal Investigator and the Centre's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Confidential Information.

Upon termination or expiry of this Agreement, the Centre or the Principal Investigator shall destroy or return to Sponsor, as per Sponsor's request, all documents, samples and material containing or relating to Confidential Information, except for one copy of Confidential Information which is to be retained in the confidential files of the Centre or the Principal Investigator for record purposes only. If requested by Sponsor, such destruction shall be promptly confirmed in writing by the Centre or the Principal Investigator to Sponsor.

The confidentiality obligations set out above shall not apply to:

a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Centre, the Principal Investigator, or the Centre's employees and/or collaborators;
b) Information that the Centre or the Principal Investigator can demonstrate by written evidence was in its possession prior to its disclosure by Sponsor or its collection or creation during or in connection with the Study;
c) Information which the Centre or the Principal Investigator received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Sponsor or any of its affiliates.
d) Information that is required to be disclosed by applicable laws, regulations or final judicial decision. The Centre shall inform Sponsor promptly, and prior to the disclore of the required information, about such requests and only disclose the information required by the applicable laws, regulations or final judicial decision.

3.12 Privacy

The Parties jointly and severally underake not to use the data otained from the Patients in connection with the Study for purposes other than outlined in the Protocol and to handle and deal with such data in accordance with all applicable laws including, without limitation, the Directive 95/46/EC and the law of December 8, 1992, concerning the protection of the private life in relation to the processing of personal data, as amended.

3.13 Publication

Sponsor recognises the Centre's or the Principal Investigator's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and shall therefore permit such publications and presentations, provided however that the Centre or the Principal Investigator shall provide to Sponsor any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that

Sponsor shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;
(b) to ensure that proprietary information is not inadvertently divulged;
(c) to enable intellectual property rights to be secured;
(d) to enable relevant supplementary information to be provided.

Authorship of any publications relating to the Study shall be determined by mutual agreement.

Sponsor may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Sponsor, whichever is later.

If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and by Sponsor.

3.14 Intellectual Property

All data, information and documents provided to the Centre or to the Principal Investigator by or on behalf of Sponsor, whether in paper, oral, electronic or other form, shall remain the sole property of Sponsor.

All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Sponsor and may be used and/or transferred by Sponsor in its sole discretion with no further payment or other obligation to the Centre or the Principal Investigator. The Centre and the Principal Investigator shall have no rights whatsoever therein.

The Centre and the Principal Investigator agree to, and to cause its employees or collaborators to, execute promptly all documents and take all such other action as may reasonably be requested by Sponsor to permit Sponsor to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Sponsor in accordance with this Agreement, and assisting Sponsor in the preparation and prosecution of patent applications. The Centre shall be solely responsible for all payments due to the Principal Investigator and/or the Centre's employees and/or collaborators according to the applicable law for any inventions transferred to Sponsor. The fees shall be deemed to include consideration for such payments by the Centre.

The Centre shall ensure that the Principal Investigator and the Centre's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

3.15 Debarment

At Present neither the Principal Investigator nor the Centre, nor any person employed thereby nor any collaborator who is involved in the performance of the Study has been debarred under Section 306(a) or (b) of the Federal Food, Drug and Cosmetic Act and no debarred person will in the future be employed or engaged by the Centre in connection with any work to be performed for or on behalf of Sponsor. If at any time after the execution of this Agreement, the Centre becomes aware that the Principal Investigator or the Centre or any person employed or engaged thereby is debarred, or is in the process of being debarred, the Centre hereby certifies that the Centre will so notify Sponsor at once, under the condition/ to the extent that the Centre is informed of the debarment.

3.16 Investigator Meetings

Before, during or after the Trial Sponsor can organise Investigator Meetings gathering investigators from different centres and locations. The Investigator or other employees of the Centre may be required to participate to such meetings. The participation to Investigator Meetings is considered as a professional

service in application of the current Clinical Trial Agreement. Such meetings will be hosted and organised by Sponsor in accordance with all applicable laws and deontological guidelines.

3. FORCE MAJEURE

Without limitation of article 2.6. above, neither Sponsor, the Centre nor the Principal Investigator shall be liable for any failure or delay in fulfilling any obligations in relation to the Study if and to the extent that such failure or delay is due to circumstances beyond the respective party's reasonable control which circumstances could not have been avoided by the exercise of due diligence. Such circumstances could include, without limitation, (i) a substantial change of the price or reimbursement conditions of the products used in the Study and (ii) a substantial change in the legal or regulatory environment to conduct observational studies in the Territory. (iii) act of God, sudden floods or natural disaster. If either Party is prevented from fulfilling its obligations in accordance with the terms of this Agreement due to force majeure, this Party shall be relieved of performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall use its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Agreement due to force majeure for a period over two (2) months, each Party shall have the right to terminate this Agreement. The termination will become effective forthwith.

4. TERMINATION

Either Party may terminate this Agreement for any safety and/or efficacy concerns by giving written notice to the other party with immediate effect. Upon receipt or giving of notice, as the case may be, Centre shall promptly terminate conduct of the study to the extent medically permissible for all patients.

Either Party may terminate this Agreement by giving written notice to the other Party, in the event that the continuation of the Study has become definitively impossible for a reason of Force Majeure as described in Article 4.

Sponsor may terminate this Agreement for any reason by giving written notice to the Centre with immediate effect.

Either Party (the Terminating Party) may terminate this Agreement if the other Party (the Defaulting Party) commits a material breach of any of the terms or conditions of this Agreement and fails to remedy such breach within thirty (30) days after receipt by the Defaulting Party of registered mail from the Terminating Party calling upon to the Defaulting Party to remedy such a breach.

In the event of termination hereunder, other than as a result of a material breach by Institution, the total sums payable by Sponsor pursuant to this agreement shall be equitably prorated to account for actual work performed to the date of termination and the cost of any non-cancelable expenses reasonably incurred, by Centre/ Investigator in accordance with the protocol, this agreement and the budget.

Pro-rata payments will be made for eligible subjects who withdraw prematurely from the Study or for eligible subjects for which not all procedures have been completed, and this in accordance to the procedures undertaken and the number of visits completed.

The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrued prior to the date of termination.

5. STATUS

The Principal Investigator is an independent contractor and nothing in any Agreement with Sponsor shall constitute him or her the employee, agent or partner of Sponsor.

6. INDEMNIFICATION

A. Sponsor Indemnity

Sponsor undertakes to indemnify and hold harmless Centre, its officers, agents, and employees, from any and all liability, loss or damage they may suffer as the result of claims, demands, costs (including reasonable attorney's fees) or judgments against them, arising out of activities to be carried out in conformance with the Protocol; provided, however, that Sponsor will not be responsible for any losses or claims, including attorney's fees and court costs, arising from any injuries of damages that are a result of :

(1) the negligence or intentional misconduct of Centre, the Investigator or other Centre employees ;
(2) activities by Centre and/or Investigator conducted contrary to the provisions of the Protocol or outside the scope of the Protocol ;
(3) violation by Centre and/or Investigator of applicable laws or regulations, or violations of any written instructions from Sponsor ; or
(4) any unauthorized warranties by Centre, Investigator or any other Centre employee relating to the Trial Medication, each of the events in clauses (1) - (4) being referred to as an "Centre Liability".

Sponsor agrees to provide a diligent defense against any claims brought against Centre, its officers, agents, and employees for which Sponsor has accepted responsibility under this Section, whether such claims or actions are rightfully or wrongfully brought or filed.

B. Centre Indemnity

Centre undertakes to indemnify and hold harmless Sponsor, its officers, agents and employees, from any and all liability, loss or damage they may suffer as a result of claims, demands, costs, including reasonable attorney's fees, or judgments against them, arising out of or resulting from an Centre Liability.
Centre agrees to provide a diligent defence against any claims brought against Sponsor, its officers, agents and employees for which Centre has accepted responsibility under this Section, whether such claims or actions are rightfully or wrongfully brought or filed.

C. Conditions of Indemnity

Any party wishing to be indemnified hereunder (hereinafter referred to as the "Indemnified Party") shall :

1. promptly after receipt of notice of any claim, complaint or the commencement of any action, suit or proceeding giving rise to the right of indemnification, notify the other party thereof in writing giving all reasonable particulars known to the Indemnified Party and enclose a copy of all papers served ;
2. permit the indemnifying party to retain counsel of that party's choosing to represent the Indemnified Party (but in the event that the indemnifying party does not choose counsel to represent the Indemnified Party, the Indemnified Party may select its own counsel, the fee and costs of which counsel will be born by the indemnifying party) ; and
3. if the indemnifying party has accepted responsibility to the Indemnified Party for such claim under its indemnity, allow the indemnifying party to retain exclusive control of any such action, suit or proceeding including the right to make any settlement ; provided that the indemnifying party will not make any settlement which could reasonably be expected to have a negative effect on the reputation of the Indemnified Party, without the prior written consent of the Indemnified Party.

7. DEFINITIONS

Unless the context otherwise requires or admits, expressions used in these conditions and in any Trial Agreement shall be interpreted as follows:

"Centre"	shall mean any site, institution or centre at which the Observational study is to take place.
"Clinical Research Organisation" or "CRO"	shall mean any organisation to which Sponsor contracts out some or all of its rights and/or duties as sponsor of an observational study.

"Declaration of Helsinki"	shall mean the latest version of the World Medical Association Declaration of Helsinki as at the date of the Study, including any amendments made during the Study.
"(e)-CRF"	shall mean any (electronic) case report form designed to collect the data for each subject during the course of the Study in accordance with the Study Protocol.
"Electronic Data Capture" or "EDC"	shall mean the process of collecting study data in a permanent electronic form.
" Ethics Committee"	shall mean the body appointed for the area in which each Centre is situated for the purpose of evaluating the objectives of, and risks associated with, observational studies from an ethical standpoint prior to their commencement.
"GCP"	shall mean the guidelines or codes relating to Good Clinical Practice specified by Sponsor for the purposes of the Study or, if none be specified, those applicable in the country or countries where the Study takes place.
"Sponsor"	shall mean the member of the Sponsor Group of Companies sponsoring an observational study either directly or through a CRO.
"Payment Beneficiary"	is the owner of the VAT number who is entitled to receive the payment of the observational study fees under the indicated VAT regime.
"Principal Investigator"	shall mean the person responsible for the conduct of the Observational Study and named as such in the Observational Study Agreement.
"Regulatory Agency"	shall mean the governmental agency or authority having responsibility for regulating the reporting of adverse drug reactions in the country or countries in which the Study takes place.
"Subject"	shall mean any patient or volunteer enrolled in connection with the Observational Study.
"the Study" or "Observational Study"	shall mean the Observational Study described or referred to in the Observational Study Agreement.
"the Study Agreement"	shall mean the Agreement between the Principal Investigator and Sponsor or the CRO setting out the terms for the conduct of the Study.
"Study Materials"	shall mean the Sponsor drugs to be administered to subjects in the course of the Observational Study or special means of administering the same.
"Study Protocol"	shall mean the Protocol or Observational Study Plan referred to in the observational Study Agreement.