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Safety, Privacy and Ethical Considerations

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Authors: Dr. Eva Schulze, Anja Wilbrandt, Anna Zirk (BIS)

Reviewers: Dr. Juan Carlos Augusto (Middlesex University, UK)
Gro Marit Rødevand (Karde AS)

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Executive Summary

D2.4 tries to summarize safety, privacy and ethical considerations related to the POSEIDON project and its users. On the one hand, it focusses on person-related issues, on the other hand technology-related issues are discussed.

Person-issues refer to the aim that POSEIDON should have a benefit to the society by increasing the quality of life. We try to increase the quality of life by enhancing the self-determination, the social participation as well as the safety and security of people with DS. Therefore we discuss issues like mobility, structure and support in daily life, friendships and leisure time activities, as well as education and work and how they can be enhanced while meeting safety, privacy and ethical standards.

Furthermore we focus on technology-related issues like usability and design aspects which should be considered. We discuss, how people with DS can be supported by technical assistants regarding their independence and autonomy in compliance with safety and ethical standards and without violating their privacy.

Safety, privacy and ethical issues should also be considered when pilots with primary users are conducted. For that reason, the procedure of the pilots is discussed from a safety, privacy and ethical perspective.

When revising this document in M21, we added screenshots of the current developmental status and explained the progress achieved as well as the technical implementation of safety, privacy and ethical considerations regarding the POSEIDON app, the cap tap and the home navigation system.
1. **Overall aim of POSEIDON**

POSEIDON aims to support both existing competencies and to regulate experienced challenges in the everyday life of people with Down’s Syndrome (DS\(^1\)). It will be developed to improve the autonomy and self-determination of people with DS and by that to increase their quality of life. It will not be developed to replace personal contact.

Developing assistive technologies for people with some kind of cognitive disabilities requires to determine the views, opinions and needs of those people (Gilbert, 2004). It is in general unanimously agreed that the wellbeing of the participants (in interviews, field trials or focus groups) and of their carers is of greatest importance to the project partners’ interests.

The development of assistive technologies is not legitimate without regarding ethical questions (e.g. Manzeschke, 2013; Rauhala & Topo, 2003; Raskind & Higgins, 1995). According to these ethical issues, three dimensions seem to be important:

1) Person, including the areas with need for support and targeted aid given

2) Technology, including requirements for a successful and safe use

3) Research, including modalities for involving people with special needs.

Please note, that the deliverable is not a literature review, as there are other literature reviews available (e.g. Jones, Hara & Augusto, 2014) written by members of the consortium.

POSEIDON will be developed and evaluated in accordance with the regulations of the Charter of Fundamental Rights of the European Union (ECFR)\(^2\) and the Convention on the Rights of People with Disabilities (CRPD)\(^3\).

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\(^1\) In the following text we use DS instead of Down’s syndrome. This is purely done for ease of reading and does not constitute a discrimination.


\(^3\) http://www.un.org/disabilities/convention/conventionfull.shtml
2. **Person-related**

Referring to Ikonen, Kaasinen and Niemelä (2009) a technology should have a benefit to the society by increasing the quality of life. POSEIDON as an assistive technology addresses this issue by increasing the autonomy and social participation of people with DS.

2.1 **Self-determination**

Autonomy means self-dependence, self-determination and independence in daily life. Due to their cognitive impairments people with DS usually experience a big extend of dependency on significant others, like relatives, teachers or general caregivers. Although the range of abilities among people with DS is big, almost everyone needs more or less help in everyday life.

POSEIDON addresses different parts of supporting the autonomy of the target group in giving back some freedom of decision-making.

**Mobility**

One big issue for people with DS is, that most of them need help to get from A to B at least for travelling routes for the first time. Difficulties occur, for instance in finding correct routes or the way on maps, but also in tackling changing plans for familiar routes, e.g. if a train is coming later or if the route needs to be changed. This can lead to some insecurity for the person itself, but also for the carer, who might be afraid that this person gets lost.

It will be explored if POSEIDON can effectively address this insecurity by giving access to context-related information. If it is of practical use POSEIDON will provide clips, photos, recorded messages with reminders, suggestions and warnings, which can be attached to specific segments of the travel plan. The system based on GPS will know where it is and will highlight this information together with the advice available for it. This holds an option for carers to track the user’s position and for instance getting an automatic message if the user arrived safely at the destination. Tracking a position could lead to specific help given by the carer, if the user has problems finding his/her way. In the end it also supports a safe travel, as the person can be found almost anywhere by the use of GPS, even if he/she got lost and is not able to say, where he/she is. Overall POSEIDON will be developed to take away some of the carers insecurity and helps to encourage a user to find his own way.

Supporting the mobility does not only affect the autonomy, it also has an impact on the social participation (see 1.2 social participation).

The screenshots display the current status of the development of the POSEIDON app and one of the main functions: the navigation. The navigation aims to increase the mobility of people with Down’s syndrome and to help them travel safely.
When selecting Routes from the main menu, a list of planned routes transferred from the home navigation system appears. A planned route has a specific start and end point and can only be used when starting from the planned location. When selecting one of these planned routes, the navigation starts. When selecting a new route, all destinations chosen for the user will be listed. The user can navigate from his/her current position to one of the destinations. The map appears and gives route guidance. Below the map there is a field with written instructions. The arrow indicates the direction.

Routes can be trained with the help of the home navigation system on a PC. It provides several functionalities. The carer can configure an address book with the addresses to be used for routes. These routes are again described by a start and an end address. The carer can customize the steps of a journey by adding photos and/or text. The user can rehearse a route made by the carer and consolidate knowledge about it at home.

**Structure and support in daily life**

Many people with DS struggle with time orientation and need guidance through their daily tasks. POSEIDON will provide a technical solution, which includes a task overview and task reminders before tasks should be done, as well as instructions on how to perform specific tasks according to the current situation. By that the technology gives a chance to complete tasks independently without the need for personal assistance.

The screenshots display the current status of the development of the POSEIDON app and one of the main functions: the calendar.
The calendar gives an overview of the events on the current day with title and time. Previous and Next can be used to see the events of other days. Passed events are displayed with less contrast, the current event is highlighted. The time left until the start of an event is indicated with a coloured bar for the last half hour before the start. An event can be pressed to see any description entered for the event. Images and an instruction list can be added to an event. Each instruction is a short text and may also have an image and/or voice message and a planned route for navigation. When an event is upcoming, the user is given a notification with the event details and how long it is until the event starts. A notification appears in the notification bar of the phone if the application is currently not open. A full reminder is shown in the application when it is opened. The notification gives a sound and vibrates until the app is displayed. A weather based message to remind the user to wear appropriate clothes comes up if the event or task is a travel for which a travel route is made.
All in all, these functions encourage the user to structure daily life more easily. If possible, the user can add and delete appointments on his or her own in the calendar app. If help is needed or if the carer wants to, appointments can be added via the Poseidon web.

2.2 Social Participation

As it is the aim of other assistive technologies not merely to replace but to facilitate inter-personal contacts (Schülke, Plischke & Kohls, 2010), POSEIDON will be developed to foster the inclusion of people with DS. DS is a well-studied condition which affects a substantial number of European citizens directly (one of 700-800 newborns having this condition; Schaner-Wolles, 2000), or indirectly (their family, carers, teachers, etc.). Although being such a well-known condition by science, it is still surrounded by negative preconceptions which make inclusion of these citizens harder.

Friendships and leisure time activities

Giving the opportunity to travel independently from one location to another can have an impact on the opportunity to build up and maintain friendships outside school or work. The dependency on parents, other relatives or carers with regard of needing help to visit somebody affects friendships and also general leisure time activities. It seems to be difficult for people with DS to extend friendships from one setting (e.g. school) to another (leisure), if these friends are located in another area, unless they are helped to visit friends or go to the same leisure activities. On the other hand it is less probable to pursue popular leisure time activities, if the opportunity to get there is not given by family members.

Providing support for independent travelling POSEIDON could help to overcome this gap and can contribute significantly to social inclusion of people with DS.

Education

POSEIDON will also help to deal with educational requirements. As already mentioned it will be developed to make travelling safer (e.g. taking the correct transport, dealing with, tickets and money, find the way from the station to school) which might result in travelling more independently not only for adults but also for students. It is planned that POSEIDON supports preparing homework for the next day by recording what the assignments for the next day are. It also will help to organize specific elements of the day (transport, preparing for school, and bringing everything they need to bring to
school like equipment for physical exercise lessons, food and drinks (if not provided at school), pencil case with content etc.) by reminders and calendar functions.

At the moment, POSEIDON tries to enhance their competencies regarding money handling with the help of an interactive table. The screenshot on the left-hand side shows the overlay for the money handling application to be used on interactive table. Real money is used to pay for the products. The products which need to be payed are displayed on a PC as shown on the right-hand side.

With the help of the money handling game the user learns the value of different products and how to pay the right amount of money. Using real coins and notes helps to consolidate the knowledge and to remember coins and bills in daily life.

Work
POSEIDON will, as a project, not only try to support their abilities, but also to raise awareness for the given competencies of people with DS. For instance the project webpage (http://www.poseidon-project.org/) highlights several biographies of people with DS from all over the world who achieved maybe more than anyone ever would have expected. It is important to emphasize, that the provided pictures and stories don’t represent a deficit-oriented perspective but rather want to underscore the strengths of people with DS. It is intended to take away the attention on the deficits and point out the abilities instead. Since underestimation of people with learning disabilities like DS has also an impact on their working opportunities. POSEIDON wants to raise the awareness for the abilities people with DS have. That means that POSEIDON might increase their chances of employment indirectly. Apart from underscoring the great spectrum of skills and competencies people with DS have, POSEIDON will support the independency and autonomy in daily life and facilitate managing daily work tasks by providing functions like notes, calendar, alarm, camera, etc. As mentioned by Wehmeyer et al. (2006) employment of people with intellectual disabilities can benefit from technology use. So POSEIDON directly might lead to greater chance of employment for people with DS.

2.3 Safety and security
POSEIDON will be developed to support the feeling of safety and security, both for carers and users. Furthermore. By giving the opportunity to track the user’s position outside home, carers will always be informed where this person is when the navigation app is used and the primary user has allowed tracking. This is important, if he/she might get lost and needs guidance on how to get back home or even needs to be located to be picked up. People with DS must consent to this, when this kind of surveillance is done in other than private settings (e.g. by a health or care service) if they have consent competence; if not their legal guardian must consent. If the person with DS is 18 years old and has a reduced consent competence, special conditions apply for Norwegian people. On 22nd of March 2013, there was a law change to make it possible for the health and care service system to track the position of persons with reduced consent competence in Norway. It says that the measures must be necessary
for avoiding or reducing a risk for harming the user. Tracking the position should be in the interest of the patient and the user. It should be empathized that the measures are reasonable in relation to the current risk, and that the measures appear to be the least restrictive alternative.

The screenshot shows the POEIDON app. It displays the level of the menu where primary users can change their preferences. As mentioned earlier that people with DS must consent to be tracked by others. Therefore they have the opportunity to switch on and off the tracking function of the POEIDON app by their own. There is no option for carers to change this setting, which means the user won’t be tracked without knowing it.

As safety is very important for disabled people good interfaces should provide a quick and reliable communication channel in order to call someone for help (Abascal & Nicolle, 2005). For this reason POEIDON will include a “panic button”, which when touched will send a message with a demand for help to the carer. When touched twice within a few minutes it will open a phone line to the carer. It will also provide location-related information to the carer like a map with the user’s location or a list of latest places visited. This information supports giving specific help and guidance to the user, if it is needed. This feature will help the user to tackle difficult situations, where insecurity or the feeling of being unsafe might occur.

If, in pilot 1, the user deviates far from the route, this will be detected and three choices will be given: A new route can be produced automatically from the current position to the original destination, the carer can be called if his/her telephone number is entered on the POEIDON web or the navigation can be ended.
3. **Technology-related**

Assistive technology in general aims to help in daily life, to give support and make some aspects of life a bit easier. From the ethical point of view the technology must provide a useful, reliable, safe and easy to use non-stigmatizing solution.

3.1 **Usability and design**

**Ease of use and usefulness**

As assistive technology aims to be a support in daily life and not a challenge, it is necessary to keep it easy to use. Particularly when it is made for people with special needs a simple to operate user interface must be provided. Therefore people with DS as possible users are involved into the developmental process and as proposed by Jones et al. (2014) their wishes, ambitions and values are taken into account.

People with DS are a very special target group. They are getting frustrated easily, so POSEIDON needs to motivate to use it and to avoid end-user frustration, which can be caused by difficulties in operations. It must allow and compensate errors, when it is used, so it needs to be an intelligent and stable system.

It must be adjustable to individual preferences and backgrounds (e.g. regarding the language) to ensure, that it is easy to use for every user and that it meets their personal (and maybe changing) need for assistance. Probably it is necessary to switch some functions on and off by helpers for individualizing, as the needs for persons with DS are quite different. Too many choices and functions working at the same time could make it difficult for the user with DS.

**Design and joy of use**

To support the wish for using POSEIDON it should have an attractive user interface. The screenshot below shows the current version of the POESIDON app (start screen). As you can see, it provides the right balance of necessary information/features and a simple interface. There are only four options displayed on the start screen: Routes, maps, calendar and preferences. This ensures that the user is not overwhelmed by too much information and that he or she can easily navigate through the menu. In addition, the main menu is easy to understand as the four main options are arranged in a square. Furthermore all four options are not only displayed with the help of text but also with an icon which helps the user to better understand what is written or even helps users without reading skills to understand the menu.
POSEIDON should not cause the feeling of being stigmatized and must not influence the felt dignity of the person using it in a negative way. For that POSEIDON has to give support when help is needed. But it must not bother people when there are able to deal with their problems on their own. Besides its usefulness it should be good-looking and make the user proud to have it. Most of the POSEIDON functions are developed so that they can be used on ordinary SMART phones and tablets.

For more information about the design principles have a look at deliverable 2.3 Designing technology for people with DS.

### 3.2 Reliability

Tackling changes of any kind is difficult for people with DS, so POSEIDON must give a reliable and stable guidance in daily life. Including context-awareness does not just make it easier to use POSEIDON, the technology can also just provide information, which is reliable and necessary for the specific situation.

“At a basic level, the protection of people starts with the safety and reliability of the equipment.” (Hoof, Kort, Markopoulos, & Soede, 2007, p. 158) Not at least for this reason it must be avoided that the system crashes down when it is used. That particularly applies to the use outside home.

To ensure the reliability of all POSEIDON systems, a four weeks lasting pilot study is conducted in UK and Germany. In Norway, the pilot will start in the middle of August. All in all, nine families (three in each country) are testing the POSEIDON systems regarding their usefulness, usability, etc. During these testing weeks, they are observed by researchers and developers. The aim is to collect as much meaningful data as possible. This includes identifying bugs as well as usability problems. After analyzing the data, the information will be used to revise the systems and the apps to ensure a reliable and stable product is provided at the end of the project.

The team at Middlesex University is currently working on a system to model the context-awareness internal logic which allows it to be translated automatically to programming code. As part of this part
of the project we are investigating the possibility to translate those modelled context-aware rules into a well-known tool which allows us to check the correctness of their logic. So the most ambitious plan is to be able to model the context-aware rules, to translate them into a correctness verification tool at the push of a button and once we are satisfied with them we can translate them into final code (in this project we are using C-SPARQL), again at the push of a button.

3.3 Transparency
POSEIDON will be developed to support people with DS in their everyday life. It is essential for potential users to know, how a technical device can affect their life in a positive as well as in a negative way (Jones et al., 2014). For that reason, all functions and potential weaknesses, for example system operations, data collection, surveillance activities and limitations provided by POSEIDON will be made public and explained to the users as best as possible. During the project insights of how POSEIDON affects the life of people with DS, the carers and other people concerned will be gained. This knowledge will provide basic information for further periods of the project or for coming to the market. This knowledge will be published to foster the ethical discourse.

3.4 Privacy
When it comes to the market, POSEIDON needs to collect a lot of data to provide appropriate options and tools for different situations (e.g. tracking the position). On the other hand it should just concentrate on relevant information, which is collected and stored. It must be guaranteed, that no third party has access to the collected data.

There are five main fields, which need to be considered, when it comes to data protection.

1) Consent: Informed consent must be given, before any data is collected.
2) Collection: Just necessary data shall be collected, avoid collecting any data just because one is able to do.
3) Storage: Just necessary data should be stored, this should be done timely limited. Data should be deleted, if the project is completed.
4) Transparency: It should be obvious at any time, which data are collected, used and stored.
5) Security: Data transfers should be made in safe technical environment. No third parties should get access to these data.

Since the pilot has already begun in Germany and the UK, these five privacy issues regarding data collection had to be considered beforehand. This means primary and secondary users had to give informed consent to take part. Furthermore, it was agreed to only collect data which is meaningful and which will be used at the end of the pilot to improve the POSEIDON systems. Participants were explained which data are collected when. Data is stored timely limited. It will be ensured that no third parties get access to the data collected.

3.5 Safety and autonomy
Technology can never be a substitute for real social contacts, especially regarding the safety of a person. Therefore it should be possible to check technical information about the system from anywhere. This enables a carer to give personal help, if the system is – for any reason – not able to do so. POSEIDON aims to make communicating for people with DS more simple instead of being a substitute for communication. Furthermore it tries to make the organization more easy which might increase the quality time with relatives and carers.
Using technology autonomously is a key requirement for any system (Jones et al., 2014). It includes the opportunity to turn off the system if one feels bothered by it (Jones et al., 2014). This requires for good knowledge of the technology and how to control it, which must be guaranteed and controlled by usability aspects. The user needs to be in the control of the system, needs to understand it’s (re)actions, feedback and provided opportunities.

3.6 Multiple user groups

The challenge which arises when different users share the same technology has to be considered. As a result the need to identify the preferences and requirements of multiple user groups and stakeholders in any number of different settings has to be prioritized (Jones et al., 2014). These requirements may compete with one another, and may need to be accommodated and balanced by prioritising the preferences and needs of some stakeholders over others. It will be carefully considered who these stakeholders are (primary/secondary/tertiary users) and how ethical issues might be affected by multi-user environments where the requirements of each user may be different and may change dynamically (Jones et al., 2014).

Project- and research-related

Especially during the process of experimentation and validation of a new technology ethical aspects have to be considered (Ezeiza, Garay, Lopez-de-Ipiña, & Aitzbier, 2008): Although the POSEIDON-project does not include medical or health-related research, but research on assistive technology development the consortium is well aware of ethical issues, which arise, especially when persons with cognitive impairments are part of a research project.

If one wants to develop technology, which meets user’s needs and abilities, it is a common technique to involve possible end users into the developmental process. As our target group is a very vulnerable user group, several ethical principles are drawn up and will be implemented within the project. The main aim is, as mentioned by Schülke et al. (2010) to realize a meaningful balance between privacy, security and safety and thereby to enhance the autonomy and self-determination of people with DS.

3.7 Procedure of pilot tests

Two pilot studies will be conducted to gather detailed feedback of the system. For that POSEIDON will be given to the families at two different stages of evolution, so that it can be used in a variety of settings (e.g., at home or at school, at work or leisure).

Each pilot will involve testing nine full kits at the same time for an uninterrupted period of a month (three kits in each country). The primary users will be students from high school, higher educated people and younger adults. There will be pre-pilot studies conducted by the development teams as part of their formal software development process (testing and validation) so that the hardware and software used during the pilots are fit for purpose and fulfill the requirements set for each specific pilot. This will involve trying the system with one family for a week to identify important elements to improve before each month long.

Pilot 1 will be an initial basic collection of services. It will include some context awareness services and some of the interface functionalities. The system will also include all features of safety and security so that it can be used safely outside the house.

Pilot 2 will be the final collection of confirmed and consolidated services. POSEIDON will be improved according to user feedback gained from pilot 1. It will also incorporate more ambitious services than
in Pilot 1, which users felt were needed and which were considered as feasible by the technical team. However suggestions for new additions will be valuable to encourage a growing developing market in this area by the commercial partners of the project and also by independent external partners who are interested in this project.

There are different approaches of how data will be collected:

1. Statistics of use and preference will be collected through logs embedded in the technology (what inclusive services are used, in which contexts, when, how often, for how long, etc.)

2. Feedback given by all of the participants through questionnaires after the pilots will be collected

3. Written diaries kept by the carers, voice recordings triggered when the product is used, simple reaction sheets (happy or sad faces) will be captured

4. Opinions from other users (teachers, employees, restaurant owners, etc.) who have interacted with primary will be collected through questionnaires

**Participation and informed consent**

According to Perry, Beyer and Holm (2008) the issue of consent is one of the most challenging ethical questions in the case of people with intellectual disabilities. It is likely that some of them are capable of making decisions for themselves and others are not (Fisher, 2003). This raises the question how can be guaranteed that a person really wants to participate (Stalker, 1998)? Therefore extra attention will be made to ensure that the persons are willing to participate and are happy to carry out the required activities. This means that appropriate information for the different competencies of users will be created to explain in simple terms what the project is about. This will also include information about how the research is conducted, possible outcomes, how personal information will be kept and the person’s rights (Dalton & McVilly, 2004). All project members will respect the person’s right to self-determination especially with regard to initial decision to participate (Magnusson & Hanson, 2003). It also will be reassured to all participants that there will be no adverse consequences if they decline to participate or later withdraw (Dalton & McVilly, 2004). Specific consent forms in easy-to-understand-language are provided to all people with DS and decisions about capacities will be made on an individual basis (Iacano, 2006).

Informed consent will also be obtained from the carers and professionals whose advice is sought for this project. Trials and user group workshops will involve different users for each technology set being examined and as a consequence, more than one set of information sheets and consent forms will be required and these will be different for the different type of users participating in the event.

**Autonomy, well-being and dignity in participation**

Every participant (person with DS, carer or expert) can quit the participation in the project at every time without giving a reason.

All appointments for pilots and interviews are at a date and time most suitable for the participant, not for the interviewer. It takes place (if the participant agrees) at his/her house, so that he/she does not need to leave and can feel as comfortable as possible in a well-known friendly environment. If it is not possible to conduct interviews or observations in people’s homes (e.g. when there are workshops abroad, where people with DS and their relatives are invited to), the project consortium ensures an appropriate and not-overwhelming environment and gives the opportunity to leave the situation at any time. In plus, the consortium aims to provide an atmosphere, in which the persons with DS can feel comfortable, valuable and honored. The main focus in research activities is on the persons and their well-being not on collecting data.
The research instruments, which are chosen for the several parts of the project are in line with the specific abilities and requirements of the person, which is asked for information. All instruments will be discussed and developed together with the National Down Syndrome association in the consortium to ensure an appropriate approach. This procedure maximizes possible advantages and minimize disadvantages for future users when interacting with POSEIDON, which should be a general aim of a technical device (Schülke et al., 2010).

All the interviewers try to respect the participant’s needs, to keep the participant’s dignity as well as to avoid confusion, frustration or harm. If it becomes clear, that the participant is stressed or frustrated by his participation, the researcher will - after consultation with the participant and and their parents/relatives/caregivers – stop the participation. The researcher will ensure that after all interviews and observations the participants are left with a feeling of success and are thanked for their work.

Attention will be paid to the need to fully support the project participants to enable them to fully communicate their needs and to ensure that the project is carried out with as little intrusion as possible to minimize possible stress. The project team will ensure that they have the full support of the participants and their carers at all times.

To ensure autonomy, well-being and dignity in participation all these points are considered by the researchers and the developers during our first pilot. To support our participants as best as possible a first line and a second line support was established. This ensures that participants know who to call if something went wrong or they experienced problems and don’t know how to deal with them.

Involving children
Our project is aimed at the part of the population which has more potential for independence. As such it will aim at teenagers (15 years upwards), young adults and mature adults, who are more potentially active (connected with education, work, exercise and socialization) and at the same time more technologically prepared and inclined. There are other issues like safety and health around very young or elderly people. Hence we will carefully select young users according to their degree of independence and within reasonable limits of safety in connection with the families and the social services related to the family.

Privacy
Since privacy is the ethical issue of greatest concern (Jones et. al, 2014), our aim is to ensure that no one’s privacy is violated whether by participating nor by future usage of POSEIDON. There are different steps within the project, where information are gathered. This is done in an online survey, in interviews with persons with DS, in group discussions in workshops, in usability and pilot-tests and in field trials.

Information gathered by the online-survey is given anonymously, the form will be completed at the internet by clicking a link. The project team does not know, who completes the questionnaire, as it also does not include any question where conclusions can be drawn about specific persons. IP-addresses are not linked to answered questionnaires.

All other steps include personal contact, so this cannot be done anonymously. After confirmation to take part, the personal data (name, address, contact information) and person data will be stored safely and the participant gets a number. Therefore no conclusions can be drawn concerning individual persons, for example when the participant completes questionnaires afterwards. Both information (a: personal data, b: information that are given in interviews and questionnaires) are stored separately. Just a limited and authorized circle of people will get access to them. It has to be transparent for the users what kind of data is stored and for what purpose and how it is used and stored. No data will be
collected without the permission of the user. Primary users less than 18 years of age will also require parent consent.

The usage of POSEIDON itself makes it essential to collect and analyze personal data. It will be assured that only relevant data will be recorded and that they will be used appropriately. Referring to Jones et al. (2014) users and their carers will have the ability to adjust their privacy level. They will be able to specify which personal data can be assessed and for which purpose they can be used.

**Reliability**

As user trust and confidence are necessary aspects of successfully interacting with a technical device, the functional capability of the technology (both Hardware and Software) will be tested several times before starting the trials, so that the participants can use a reliable and stable version of the system at any stage. Furthermore the user should completely understand to what extent he/she can rely on POSEIDON (Ikonen et al., 2009). Our development team will take all the necessary steps on testing and validation and these steps will include, for example, the technology being tested by families as part of pre-pilot testing exercises. There will also be a technical support in every country, which can be called and will solve problems as fast as possible. If technical problems are experienced the technical team will ensure that the participants are aware that it is the fault of the project not theirs.

### 3.8 Equality of access

As proposed by Jones et al. (2014) aspects of equality will be taken into account. As proposed by Jones et al. (2014) aspects of equality will be taken into account. POSEIDON will be designed simple enough so that it can be used by the widest possible range of users. For this reason “different potential levels of cognition, competence and cognitive ability of primary users” (Jones et al., 2014) will be considered. Regarding these individual differences, users will be able to personally customize POSEIDON (within their framework of capabilities or with the help of their carers) to their preferences and special needs.

If it comes to the market, there is a need for different marketing strategies (for example leasing or paying a monthly amount instead of paying the whole amount at one time) to avoid the financial exclusion of those who do not have much money but would definitely benefit from using the system. This approach follows the principle of equality which prohibits irrelevant differentiation and realizes a fair access to POSEIDON (Schülke et al., 2010) Part of the work will consist on engaging with local authorities and government to assess the feasibility that financial help is provided to those financially disadvantaged.

For the research period all technological equipment which is needed for testing and piloting will be provided by the consortium to avoid excluding persons, which do not own this technology.

### 3.9 Advisory committee: Experts on ethics, data protection and target group

- **Ethics advisor:** Dr. Juan Carlos Augusto (Middlesex University, United Kingdom)
- **Research-related data advisor:** Dr. Eva Schulze (Berlin Institute for Social Research, Germany)
- **Country specific data advisor:**
  - Christine Schniersmeier (Arbeitskreis Down-Syndrom e.V., Germany)
  - Lars Erik Brustad (Norwegian Network for Downs Syndrome, Norway)
  - Vanda Ridley (Downs Syndrome Association, United Kingdom)
Technology-related data advisor: Lars Thomas Boye (Tellu AS, Norway)

Experts on target groups: Arbeitskreis Down-Syndrom e.V. (Germany)
Norwegian Network for Downs Syndrome (Norway)
Downs Syndrome Association (United Kingdom)

3.10 **State-level ethical issues**

**Germany**

The German work in connection to user involvement in surveys, field trials or focus groups will follow accepted international ethical practice.

High standards related to data protection issues and human ethics are based on the suggestions of the German Research Society.

The project will be reported by the Berlin Institute for Social Research to the National Data Protection Agency in Berlin (Dr. Alexander Dix). All requirements for data protection, user involvement and dignity issues will be followed in regard to every person being part of the evaluation.

The relationship between researcher and participant is based on the ethical codex of the German Society of Nursing Sciences. This codex includes basic issues, e.g. the necessity of a research project, information about the aim of the project, possible exit strategies, prevention of stress and harm, which will be followed with respect to the participant’s rights and are meant to maintain a good mental and physical health of these volunteers. Participants with reduced consent competence will only be involved, if a responsible person agrees to their participation additionally. Consenting of the carer will not override the dissenting of the potential participant.

**Norway**

The work in Norway in connection with focus groups and testing will follow accepted international ethical practice. For primary test users with reduced consent competence the guidelines from 2005 made by The Norwegian National Research Ethics Committee for Medicine and Health (NEM) for persons with reduced consent competence will be used. In addition to international ethical guidelines and practice the Norwegian Guidelines for Natural Science and Technology will be followed; (http://www.etikkom.no/Forskningsetikk/Etiske-retningslinjer/Naturvitenskap-og-teknologi/). These guidelines are supplemental to existing international ethical research guidelines.

The project will be reported by Karde to the Norwegian Data Protection Agency. International and Norwegian requirements for data protection and confidentiality will be followed both in regards to persons with DS and secondary users, and collection and storing of data. The Personal Data Act for Norway requires that the controller ensures satisfactory information security with regard to confidentiality, integrity and treatment of information: http://www.ub.uio.no/ujur/ulovdata/lov-20000414-031-eng.pdf.

This project is mainly a technological project. There will be no treatment of medical nature. The primary test persons with DS have a medical diagnosis of intellectual disability. One of the criteria for this diagnosis is problems with adaptive skills in functions/abilities of daily life. In the project we will try to help persons with DS in mastering certain aspects of daily life. A form for request obligation will be sent to the appropriate Norwegian regional committee for medical research ethics. If the committee should be of the opinion that a full evaluation is required, the appropriate information will be submitted for review and guidelines for medical research ethics will be followed. Karde has conducted several projects involving persons with reduced cognitive functions. These projects have
primarily involved elderly persons with intellectual disabilities and memory problems/dementia. In connection with these projects Karde has gained considerable experience in communicating with persons with intellectual disabilities, their next of kind and helpers. Karde also has great experience creating easily understandable information sheets and consent forms for test of persons with intellectual disabilities. They will use this experience to ensure that test persons understand the meaning and principles of the study and that they are as comfortable as possible with participating.

The involvement of The Norwegian Network for Down Syndrome in planning, making Norwegian information sheets and testing, will further ensure the use of good methods.

**United Kingdom**

The work in the United Kingdom will follow accepted ethical practise with respect to the work with the volunteers with disabilities and their carers and also with respect to the collection and storing of data on the participants.

Approval for the research will be sought from the Middlesex University Ethics Committee and will follow the *Middlesex Code of Practise for Research* (http://www.mdx.ac.uk/Assets/Code%20of%20Practice%20for%20Res-July2011.pdf).

The research will make use of the existing best practise with respect to the participants’ rights (http://www.eis.mdx.ac.uk/research/groups/Alert/Ethics_Research/forms.html).

The Middlesex Guidelines closely follow the code of the British Psychological Society (http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf) and are most suitable for the non-invasive research to be carried out on this project.

Middlesex University has a record of carrying out participative research with people with disabilities and other vulnerable people. We will use the knowledge from this work to ensure that all the volunteers are enabled to participate only if they want to and that the research is an enabling enjoyable experience for all who take part.

Particular attention will be paid to the need to communicate with the volunteers in a suitable way and to ensure that the tests do not put any volunteer under undue stress. Middlesex University has through its work in the EDEAN: European Design for all eAccessibility Network links to the National Disability Authority of Ireland, we will therefore follow their *Ethical Guidance for Research with People with Disabilities* (http://www.nda.ie/cntmgntnew.nsf/0/D6EFA30A02A47B14802570660054EC16?OpenDocument), particular attention will be paid to the advise on working with people with intellectual disabilities.

The attention that Middlesex University pays to the need to work with people with disabilities in an ethical way can be seen by the talk given at Middlesex, ‘The Practical Application of Ethical Guidelines for Participative Research’ Workshop held at Middlesex University, London, UK on Monday 23rd January 2006, (http://www.humanity.org.uk/articles/politics-culture/ideologyprofessionalism-research-disabled). We will follow the ideas presented in this research and will act in a professional and supportive way with all the project staff and volunteers.
Literature


Magnusson, L., & Hanson, E. J. (2003). Ethical issues arising from a research, technology and development project to support frail older people and their family carers at home. Health & Social Care in the Community, 11(5), 431–439.


Appendix A
Information sheets for primary users (people with DS) used for interviews in January 2014
Example: United Kingdom

Easy Read Information Sheet

Our Project
We are looking for people with Down’s syndrome to help us with our project.

What the Project is about?

- We want to develop technology to be used for smart phones, ipads, tablets and PCs to help you in your daily routines.

- We want you to tell us where you most need help and support.

- Ask your parent/carer to explain more about the project if you need to. Then think about if you want to help us.
• You can also ask Vanda Ridley from the DSA who is member if the project team for more information.

Why I am asking you to help?

• We are asking for your help because you have Down’s syndrome.

• We want you to tell us about the things you do every day and where you need most help and support.

• We will give your information to inventors who want to make phone and iPads that can help you with the things you do every day.

• You don’t have to say yes to help.

• It’s ok to say no.

If you want to help what happens next?

• If you decide to help we will set up a time to meet you. At the meeting we will ask you questions about things that you do every day.

• You can ask for a parent or carer to be present.

• The meeting will take 1 ½ hours.

• We will record your answers.

• It’s ok to say you don’t want to answer a question.
• It’s ok to say you want to break for a pause.

• It’s ok to say you want to stop the interview.

• It’s ok to say you don’t want your answers recorded.

• We will write a report about the information we collect.

• We will show you what we have written and you can change anything you do not like.

• We may write about the project in magazines.

• We will change your name so no one will know what you have said.

• We will not share your personal information with anyone.

• Your personal information will be kept in a safe place and only one person from the project team will have access to it.

• One year after the project is finished your personal information will be destroyed.

• You can tell us if you don’t want us to use your answers.

• If you are unhappy about anything you can tell us.
• You can ask us any questions about the project.
Appendix B
Consent forms used for interviews in January 2014

Consent Form
Poseidion Project

Please tick the appropriate box:

I am participating in this project as a

☐ Primary User (person with Down’s syndrome)
☐ Secondary User (parent or carer of person with Down’s syndrome)
☐ Tertiary User (professional supporting people with Down’s syndrome)

Thank you for considering taking part in this research. If you have any questions please ask a member of the project team before you decide whether to take part. You will be given a copy of the Consent Form and Information Sheet to keep and refer to at any time.

Please tick or initial each box to agree to below.

☐ I confirm that I have read and understood the information sheet dated…… (version…..) for the above study

☐ I have had time to consider the information, ask questions and have had these answered satisfactorily.

☐ I understand that my participation is voluntary and I am free to withdraw at any time without giving any reason, without my care or legal rights being affected.

☐ I understand that if I withdraw from the study, the data collected up to that point will be destroyed.

☐ I understand that my personal data will be safely stored and destroyed one year after the end of the project.

☐ I understand that the data may be published but this will be without reference to my personal details.
☐ I agree to the interview being audio recorded if necessary so that my comments can be typed up and used for research data after I have verified a summary of the interview

☐ I agree to take part in the study

Participant ________________________________

I am over 16 years of age [ ] tick

Signature_______________________________

Date______________________________

Parent/Guardian, please sign here (if the participant is under 16 or unable to sign):

Name ________________________________

I am over 18 years of age [ ] tick

Relationship to participant ________________________________

Signature_______________________________

Date______________________________

Name of Researcher/Interviewer (please print):
Guidelines for inclusion of adult people with missing or reduced competence to consent in health research

1. It is presupposed that the requirements that generally apply to research that includes people, also form the basis for research that includes people with reduced or lack of consent competence, to the extent that they are relevant.

2. Persons who are not able to give informed consent should generally only be included in the research if:
   a) it cannot be performed on individuals who are able to consent, and
   b) it can be substantiated that the research is of direct and significant benefit to the individual or group being studied.

3. In research where knowledge can benefit the group in question, but the direct benefit to the individual that is included is absent, uncertain or in the distant future, it is essential to include people who cannot give informed consent, the risks and load entailed by the study are negligible for the person being included.

4. When people who communicate pain, discomfort or well-being in a peculiar manner, are included in the research, it is important that the study uses methods that take into account the subject's specific communication means. It is particularly important that the expression of pain and discomfort is captured. A person with a good knowledge of the relevant person's ways of expression should be consulted, so that one can best interpret the person's speech and sign and side effects.

5. The greater the risk or discomfort a project entails, the more stringent the requirements to the subject's understanding of what the project means, should be.

6. An assessment of consent should not be based on group identity. People with the same disease or the same intellectual disability may have different consent competence. Whether a person is competent to give consent or not, must be shown through an individual assessment of each potential participant.

7. If the tests are used for the assessment of consent, it is important that these are not be used mechanically, but only as a means to identify people who are in a situation where consent competence need careful consideration. When a person's skills may be situational and project dependent, the person's understanding ability always must be considered in relation to the current study.

The Responsibilities of the Project Manager

8. The project manager should always consider on an individual level if potential subjects / informants are consent competent in relation to the current research project. If there is doubt about consent competence for any of those considered as possible participants, the project will include in the protocol / application to the REK (Regional Committee on Research Ethics) a plan for how consent competence should be considered.

9. Since consent competence is not only depending on personal circumstances, but also on how the current project is presented, the project manager must always consider whether special information facilitation and information procedures can make persons more able to consent to participation on their own behalf.

10. Although a potential test subject does not have sufficient understanding capacity to give consent, it is essential that the project manager is doing everything possible to explain what the current project involves (purpose, risks and potential benefits), if the trial subject or informant is not is completely without the ability to understand.

These guidelines are made by The Norwegian National Committee for Research Ethics for Medicine and Health Research for information and consent procedures for persons with reduced consent competence. It is based on the health research law in Norway and the OVIEDO convention. These guidelines are often used also for other research than health research. These guidelines will be adopted in POSEIDON unless the local government requires something different or additional. All partners of POSEIDON are experienced on using consent and information sheets from previous projects they have participated from.
11. If a person with limited ability to understand is considered competent to give informed consent to participate in a particular study, the project manager should consider whether a person who is independent of the research project, should be present at the information and consent process.

12. Any expression, both verbally and non-verbally, from a subject who opposes participation, both prior to and during the trial must be respected.

13. Where there is doubt about the person considered for inclusion in a project, understands enough of the project and can safeguard his/her own interests, the project manager to the greatest extent possible, and as long as the person does not oppose this, consult with next of kind about what can be in accordance with his or her interests. A reservation of the next of kind should be given considerable weight. Although the next of kind accepts that a person with reduced or lack of consent competence is included in the project, this never makes redundant a thorough and independent review by the project manager’s about the interests and welfare of this person is dealt with in a satisfactory manner. An acceptance of next of kind never invalidates expressed reluctance to participation from the relevant subject, whatever mental condition and competence of the person.

14. If next of kind does not exist or for other reasons is not natural to contact next of kind, the project manager should check if there is another person who knows the research subject or informant well (family, friends, caregiver / health care personnel), who can be consulted on the advisability of to include him or her in the current study.

15. When it can be questioned whether the person considered included in the project is competent to give consent, and he/she is a patient and has a person being responsible for the treatment who is another than the researcher, the project manager should consult the treatment responsible person to discuss the appropriateness of including the patient in research. Or they should then discuss how to provide information and conduct the project in a satisfactory manner.

16. When it should be decided whether the current research project purposes can be said to have a clear positive impact on the individuals or groups being studied, the project manager should consider consulting relevant user groups. Their potential advice must however be regarded only as a guide and cannot replace an individual assessment of the risk / benefit for the individual subject or informant.

17. In studies without potential direct benefit of the person being included, and it is therefore presupposed that research participants only are exposed to insignificant risk /load, the project manager should consider the use of a person who knows the person well. This person must be independent of the study and should be able to decide whether the risk / load the study may expose the individual for, really is insignificant to him/her.

18. If the subjects or informants during the study will be able to give consent, the project leader should again provide information about the study and obtain consent for continued participation. If he/she wants to withdraw from the study, all data about that person deleted unless there are compelling reasons not to do this.