Informed consent

Title of the Project: "Evaluation of AsTeRICS Technologies" in the course of the research cooperation with the AsTeRICS Academy project
Organization: AsTeRICS Academy, Department of Embedded Systems, University of Applied Sciences Technikum Wien, Vienna, AUSTRIA
Principle Investigator: DI Christoph Veigl, Department of Embedded Systems, University of Applied Sciences Technikum Wien, Vienna, AUSTRIA

This Informed Consent Form has three parts:

- **Information Sheet (to share information about the research with you)**
- **A short description of the provided Assistive Tools and possible risks**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction
Assistive Tools, developed at the Department of Embedded Systems at the University of Applied Sciences Technikum Wien, Vienna, Austria, are capable of assisting people with limited motor capabilities in different tasks of life.

Purpose of the research
In course of the AsTeRICS Academy project, several affordable Assistive Tools have been developed, which allow computer access for people with reduced motor capabilities. In that way, people with severe upper-limb motor impairments, e.g. people with tetraplegia or people having muscular dystrophy, are able to control a mouse cursor, type letters, surf the internet or play computer games and control electric devices. The reason of this study is to find out:

- which type of users (regarding impairment/functions) can meaningfully use the provided Assistive Tools and in which way,
- how users can work with the provided Assistive Tools in efficient ways,
- how long it takes to learn the handling of the provided Assistive Tools and
- if the user enjoys the use of these tools.

Furthermore, it is important to find weaknesses and suggestions for improvements together with the users and based upon their feedback.

The research should show the potential of the developed Assistive Tools for people with severe motor impairments.

Type of Research Intervention

This research will involve using the provided Assistive Tools in different scenarios like writing, internet browsing or gaming and the documentation of these investigations. Additionally, after you have tested and completed these scenarios, you will (be asked to) answer a questionnaire about the use of the tools.

Participant Selection

You are being invited to take part in this research because we think that you are a potential user of Assistive Tools or a suitable organization and that you could benefit from these devices or programs. Your feedback can contribute much to our understanding of the needs of potential users and to future developments of the tools.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You can of course withdraw from your cooperation at any time without any consequences for the future.

Procedures

If you accept being part of the study you will be asked to use/try out the provided Assistive Tools (will be ticked as appropriate by local investigator) in different scenarios like typewriting, browsing the internet, gaming, configuring different settings of the Assistive Tools or the general use of a PC.

These investigations will be documented to record the status and functionality of the provided tools.

After you have tried out the provided Assistive Tools in the different scenarios you will be asked to fill out the questionnaire. You may answer the questionnaire by yourself, or it can be read to you and you can say out loud the answer you want the investigator to write down. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question.

The information recorded is confidential, your name is not being included on the forms, and only a number will identify you.

In the questionnaire you will be asked e.g. if you had any (physical) problems while using the provided Assistive Tools, if there were any technical problems while using the tools, how long the average usage time was, what in your opinion can be improved or the like. Furthermore, at the end of the questionnaire you will be asked to answer some questions concerning the usability of the

tools, e.g. if you found the system complex or easy to use, if you felt very confident using the system or if you needed to learn a lot before you could use the devices and/or software.

Duration

The whole procedure will last about 30-60 minutes. During that time you will try out the Assistive Tools and afterwards answer a questionnaire about the use of the tools.

Benefits

Your participation in this study will help us to find out for which users the developed Assistive Tools can be useful, and to find out possible improvements and weaknesses of them. With the outcome of this study, our tools can be improved and adapted to the needs of more potential users. Thus, more users could benefit from these devices by enabling the use of a personal computer which allows communication, environmental control, gaming and leisure activities and working within the "information society".

Reimbursements

You will not be provided any incentive to take part in the research.

Confidentiality

We will not share any personal information about you to anyone outside of the research team if you do not want us to do. For scientific and non-scientific publications all data and photos will be anonymized if the use of such data or photos has not been explicitly granted by you.

Sharing the Results

The results of this study will be published through scientific publications and non-scientific publications, e.g. contributions on official University homepages. Furthermore they will be used for teaching purposes.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. At the end of the questionnaire you will have the opportunity to review your answers, and you can ask to modify or remove some portions of those.

Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact:

Team of AsTeRICS Academy project – office@asterics-academy.net

Part II: Short description of the provided Assisitive Tools and possible risks

In particular, two assistive modules will be provided for this study: the AsTeRICS FLipMouse and the AsTeRICS FABI-Box:

The **FLipmouse** (Finger- and Lip Mouse) represents an equivalent alternative to a PC mouse. It offers a highly sensitive mouth-piece, which allows people with very limited range of motion and low muscle forces (e.g. in case of late-stage muscular dystrophy or paraplegia) to use a personal computer. The FLipmouse can be used in two ways:

1. As a *Lipmouse***.** In that case the mouse cursor is controlled by operating the joystick of the module with fine lip movements and the mouse clicks are be performed by sip and puff actions or via external switches.
2. As a *FingerMouse*. In that case the mouse cursor is controlled by operating the joystick of the module with fine finger movements. The mouse clicks are performed with external switches.

The **FABI-Box** (Flexible Assistive Button Interface) is an interface box for the computer which allows the creation of mouse- and keyboard functions via up to 6 button switches. Thus, it is possible to assign one switch to each mouse function (left click, right click, wheel up, wheel down, drag, move any direction) or to assign one switch to desired key presses. By pressing the switch, one or a series of keys can be pressed, for example to enter a password phrase for a login screen.

The scenarios for the evaluations:

❑ Use of the FLipmouse as mouth-controlled cursor (internet browsing, typing, playing games)

❑ Use of the FLipmouse as finger-controlled cursor (internet browsing, typing, playing games)

❑ Use of the FABI-Box with 2 or more switches for different tasks (internet browsing, typing, playing games)

Involved Risks when using the FLipmouse:

The ergonomic positioning of the FLipmouse is essential to avoid pain and to enable long-term usage. A bad positioning promotes muscle cramps or muscle pain due to unnatural posture of the arm, hand or head respectively.

When the FLipmouse is actuated with the mouth/lips, a lack of hygiene can cause problems, especially when the mouthpiece is used by more than one person. If the mouthpiece is not sufficiently cleaned it is possible that:

- a skin rash arises
- viruses and bacteria are transmitted, causing diseases
- mould develops in and around the mouthpiece, causing danger to health

Instructions for correct use and hygiene

The risks involved when using the FLipmouse can be minimized by respecting the rules for correct use and hygiene. You will be given an additional document with detailed instructions for the usage and cleaning of the FLipmouse. These instructions are obligatory and must be well understood and applied when the device(s) is/are used by individuals.

When the FLipmouse module is used with the fingers:

- position the arm/fingers in a natural way and with support from the table
- position the module closely to the finger, so that moving the joystick is easy and feels natural for the user

When the FLipmouse module is used with direct contact to mouth/lips:

- use one separate mouthpiece per user
- replace the filter tip whenever saliva has entered or dirt has formed
- clean the mouthpiece whenever saliva has entered or dirt has formed
- read and apply the provided instructions for correct positioning and hygiene (see User manual FLipMouse)

Part III: Certificate of Consent

I agree to participate on the study “Evaluation of AsTeRICS Technologies”.

I have read the forgoing information, or it has been read to me. I have had the opportunity to ask question about it and any questions I have been asked have been answered to my satisfaction.

The possible risks of using the provided Assistive Tools have been explained to me and any questions I have been asked concerning these risks have been answered to my satisfaction. The instructions for the use of the provided Assistive Tools to avoid these risks have been explained to me and will be respected.

I hereby agree that all data and results generated through this study are recorded and can be published. My personal data will by anonymized. The provisions of the data protection law, namely the European Convention on data protection, in the valid version are observed.

I consent voluntarily to be a participant in this study. It can withdraw from my cooperation at any time without any consequences for the future.

Furthermore, I confirm receiving a copy of the Informed consent consisting of the Information Sheet and the Certificate of Consent.

Print Name of Participant: _____

Signature of Participant: _____

Date _____
Day/month/year

If illiterate or not capable of signing[1]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. The participant tries out the Assistive Tools provided and will use the PC in different use cases (e.g. general use, surfing the web, playing games)
2. The participant answers the questionnaire given.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher/person taking the consent _____

Date _____
Day/month/year

[1]A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).