

 École d’optométrie

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|  | **Information and Consent Form** |
| **Research project title:** | Development of a Core Set for Deafblindness using the International Classification of Functioning, Disability and Health - Phase 4 |
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**1. Introduction**

We invite you to participate in a research project. However, before agreeing to participate in the project and signing this Information and Consent Form, please take the time to read, understand and carefully consider the following information.

This form may contain words that you do not understand. We invite you to ask any questions that you feel might be helpful to the researcher in charge of the project or to a member of the research team, and to ask them to explain any word or information that is not clear to you.

**2. Nature and objectives of the research project**

We are working on developing a standardized way to evaluate the functional abilities of persons living with any form of combined vision and hearing difficulties (deafblindness). We are using a framework developed by the World Health Organization to establish the best way to build such an evaluation. To accomplish this, we have conducted three studies to help us build such a standardized evaluation, and now we want to use this evaluation with persons living with deafblindness, so we can test whether it is working the way it is intended. To carry out this research project, we intend to recruit 30 participants, men and women, aged 18 or older.

**3. How the research project will proceed**

**3.1 Location, duration, and number of visits**

This research project will take place online (using the video-conferencing platforms Zoom or Teams), to your preference. Your participation in this project will involve one single session that should last around 90 minutes.

**3.2 Nature of your participation**

We will provide you access to this consent form in your preferred format once you express interest in our study. The team is available to explain or summarize the content for you if you wish. If you can provide written consent, you can sign and send this consent form (in paper or electronic format) to the research team. If you prefer, you can provide verbal or signed consent at the beginning of the interview, which we will record remotely using Zoom or Teams.

By participating in this research project, you will complete a standardized clinical assessment, including demographic information, such as your age, sex, level of education, and the causes of your vision and hearing impairment. The assessment then explores aspects of your physical functioning, and any limitations you may experience in being active or restrictions you perceive in participating. We will also explore environmental barriers you may experience. Then we will ask you questions from three standardised questionnaires: the Lawton Brody Instrumental Activities of Daily Living scale, the Mini-Mental State Exam, and the Centre for Epidemiological Studies Depression scale. The interview should take approximately 90 minutes in length.

To participate in this research project, you will need either a telephone, a tablet or a computer, as well as an Internet connexion. The interview will be video recorded in order to facilitate our the transcription of the interview content for our data analysis later on.

By participating, you will be providing useful information that helps us develop a standardized evaluation for persons living with deafblindness. The outcome will help deafblind people around the world because we can establish standardized terminology that can be used in all countries when planning of services and support for persons living with deafblindness.

**4. Advantages associated with the research project**

You may benefit personally from participating in this research project, but we cannot guarantee it. The results obtained nonetheless will contribute to the advancement of scientific knowledge in this field of research.

**5. Inconveniences associated with the research project**

Time spent participating in this research project is the main inconvenience associated with this research project.

**6. Risks associated with the research project**

Your participation in this research project will not involve any known risks. However, you may feel tired as a result of participating in this project. Some questions may bring out negative emotions in you. If this happens, you can discuss it with a member of the research team who can refer you to health professionals or provide you with a list of local resources that can help you. You are invited to request a break whenever needed and can withdraw from the study at any time.

**7. Voluntary participation and right to withdraw**

Your participation in this research project is voluntary. You are therefore free to refuse to participate in it. You may also withdraw from this project at any time, without having to give a reason, by informing the research team.

The researcher in charge of the project or the *Comité d’éthique de la recherche clinique* may end your participation, without your consent. This may happen if new findings or information indicate that your participation in the project is no longer in your best interest, if you do not follow the research project instructions or else if there are administrative reasons for abandoning the project.

If you withdraw or are withdrawn from the project, the information and material already collected in the context of this project will nonetheless be stored, analyzed, or used to ensure the integrity of the project.

Any new knowledge acquired during the course of the project that could have an impact on your decision to continue participating in this project will be communicated to you quickly.

**8. Confidentiality**

During your participation in this research project, the researcher in charge of the project and their research team will collect and record the information about you in a research file. They will only collect information required for meeting the scientific purposes of the project.

This information may include data about your current and past health status, lifestyle, responses to questionnaires and your answers to the interview. Your file may also include other information including your name, gender, date of birth and ethnic origin.

All information collected will remain confidential. In order to preserve your identity and the confidentiality of this information, you will only be identified using a code number. The key to the code linking your name to your research file will be kept by the researcher in charge of this research project.

The research data will be stored for at least 7 years by the researcher in charge of the research project.

Research data may be published or shared in scientific discussions; however, it will not be possible to identify you.

For the purposes of monitoring, control, safety and security, your research file may be consulted by a person mandated by regulatory agencies, as well as by representatives of the *Université de Montréal* or the *Comité d’éthique de la recherche clinique*. All of these individuals and organizations adhere to a confidentiality policy.

You have the right to consult your research file to verify the information collected and to have it corrected as needed. Moreover, access to certain information before the end of the study could mean that you shall be withdrawn from the study, to maintain its integrity.

**9. Participation in future research projects**

Would you agree to be contacted by the researcher in charge of this research project or a member of their research team to propose to you to participate in other research projects approved by the *Comité d’éthique de la recherche clinique* of the *Université de Montréal*? Of course, you will be free to accept or refuse to participate in any future research projects.  **Yes No**

**10. Secondary use of research data**

Would you agree that your research data be used by the researcher in charge of this research project to carry out other research projects in the field of optometry?

These research projects will have been evaluated and approved by the *Comité d’éthique de la recherche clinique* of the *Université de Montréal* before they are carried out. The Committee will also ensure its ongoing monitoring. Your research data will be stored securely on computer servers at the Université de Montréal. In order to preserve your identity and the confidentiality of your research data, you will only be identified by a code number and all measures will be taken to maintain the confidentiality of this information.

Your research data will be kept as long as it can be useful for the advancement of scientific knowledge. When it is no longer needed, your research data will be destroyed. In addition, note that at any time, you can request the non-use of your research data by contacting the researcher responsible for this research project.

Do you agree to your research data being used under these conditions? ** Yes  No**

**11. Compensation**

As compensation for your participation in the research project, you will receive an amount of 50 dollars.

**12. Should you suffer any harm**

By agreeing to participate in this research project, you are not waiving any of your legal rights, nor discharging the researcher in charge of the research project, Deafblind Ontario Foundation and Canadian Hearing Services or the *Université de Montréal* of their civil and professional responsibilities.

**14. Identification of contact persons**

If you have any questions about the research project or if you wish to withdraw from it, you may contact the researcher in charge at the following telephone number or email address: Dr. Walter Wittich, 514 343-7962, walter.wittich@umontreal.ca

Any complaints regarding this research project can be addressed to the ombudsman of the *Université de Montréal* by calling 514-343-2100 or by email: ombudsman@umontreal.ca. The ombudsman accepts regular and collect calls from 9am to 5pm and speaks French and English.

**16. Monitoring of ethical aspects of the research project**

The *Comité d’éthique de la recherche clinique* of the *Université de Montréal* has approved the research project and will ensure its ongoing monitoring.

**Consent.**

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1. **Participant’s consent**

I have read the Information and Consent Form. Both the research project and the Information and Consent Form have been explained to me. My questions have been answered and I was given sufficient time to make a decision. Upon reflection, I consent to participate in this research project in accordance with the conditions stated above.

Name and signature of the participant Date

1. **Signature of the person obtaining consent, if other than the researcher in charge of the research project**

I have explained the research project and the terms of this Information and Consent Form to the research participant, and I have answered all questions.

Name and signature of the person obtaining consent Date

1. **Signature and commitment of the researcher in charge of the research project**

I certify that this Information and Consent Form was explained to the research participant, and that the participant’s questions have been answered.

I undertake, along with the research team, to respect that which was agreed upon in the Information and Consent Form.

Name and signature of the researcher in charge of the research project Date