IRB APPROVED
Mar 23, 2021

RESEARCH PARTICIPANT CONSENT FORM

TITLE: Evaluation of efficacy and effectiveness of hearing aid technology

PROTOCOL NO: IRB Protocol #20210549

SPONSOR: Sonova Canada Inc.

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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. It is important that you read the following information in order to decide whether or not to take part in this research. You may take home an unsigned copy of this consent form to think about or discuss with your health care provider, family or friends before making your decision.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether or not you take part is entirely your decision.
- If you don't take part in the research, it won't be held against you. Your decision to not participate will not result in any penalty or loss of benefits to which you are otherwise entitled.
- You can participate now and later decide not to participate, it will not be held against you. Your decision to withdraw will not result in any penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, please ask questions.
- Ask all the questions you want before you decide.
- Hygiene and safety measures at the research site are in compliance with health authority regulations.

How long will I be in this research?

☒ This study consists of ☐ 1 ☐ 2 ☒ 3 ☐ 4 ☐ 5 ☐ 6 appointments with a maximum duration of ☐ 30 ☐ 60 ☒ 90 ☐ 120 minutes each at following location:
- ☐ Sonova Innovation Centre Toronto, 2-3105 Glen Erin Dr, Mississauga, Ontario L5L 1J3
- ☒ Unitron Hearing, 20 Beasley Dr, Kitchener, Ontario N2E 1Y6
- ☐ remotely (i.e., from your home).

☒ There will be approximately
- ☐ 1 ☐ 2 ☒ 3 ☐ 4 weeks or
- ☐ 1 ☐ 2 ☐ 3 months between each appointment.

☒ You will be asked to wear the devices while going over your everyday activities (home trial) for ☐ 1 ☐ 2 ☒ 3 ☐ 4 ☐ 5 ☐ 6 weeks.

☒ You will be asked to complete a questionnaire online (approximately 30 minutes).

☒ You will be asked to complete a questionnaire (approximately 30 minutes) and return it to
- ☐ your hearing aid clinic who will forward it to the study sponsor
- ☐ Sonova Innovation Centre Toronto, 2-3105 Glen Erin Dr, Mississauga, Ontario L5L 1J3
- ☒ Unitron Hearing, 20 Beasley Dr, Kitchener, Ontario N2E 1Y6
- ☐ innovation.toronto@sonova.com

While participation time may vary based on individual health conditions, your participation schedule will be discussed with you to ensure that it works for your schedule. Your participation depends on your individual health conditions.

Why is this research being done?

The purpose of this study is to evaluate the efficacy and effectiveness of existing and new investigational hearing aid technology and accessories, including hardware, software and fitting characteristics. Investigational means a device that has not been approved for use by Health Canada.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include a study intake form (asking for your contact information, language and musical skills, education, audiologic and health conditions that may affect the tasks of the experiment, daily listening situations and your availability to test devices). You will also receive following assessments (please refer to ticked boxes):

- ☒ Examination of the ear: ☒ Otoscopy (visual check) ☐ Temperature ☐ Humidity
- ☒ Tone and speech audiometry (hearing test)
  - ☒ alternatively: Please provide us with your most recent audiogram (hearing test) or advise your hearing aid clinic to do so.
- ☒ Real ear measurement (ear canal acoustics)
- ☐ Middle ear acoustics
- ☐ Otoacoustic emissions (ear canal echo)
- ☐ Evoked potentials (brain response towards sounds)
- ☐ Cognition
- ☐ Vision
- ☐ Walking ability

The study will include following procedures (please refer to ticked boxes):

☒ You will be asked to use following devices

- ☒ Hearing instrument
  - ☒ with standard ear tips (“domes”)
  - ☒ with ear pieces for which we will take an ear impression
- ☒ Hearing instrument charger
- ☒ Remote microphone technology
- ☒ Streaming device
- ☒ Hearing instrument remote control
- ☒ App on a smartphone/tablet

with existing or investigational technology. Hearing aids and accessories will be programed by trained research staff according to your hearing test.

☐ You will be asked to wear devices that use non-invasive biometric sensor technology collecting and/or measuring following data:
- ☐ Heart rate
- ☐ Walking/motion/steps
- ☐ Muscle contraction/movement
- ☐ Light
- ☐ Sound
- ☐ Blood oxygen (fNIRS technology)

☒ You will be asked to complete following tests or tasks that evaluate hearing instrument and/or biometric sensor technology:
- ☒ Speech perception test (listening to and repeating a sentence, word or phoneme in quiet or noise)
- ☐ Localization test (hearing a sound and indicating the sound source direction in quiet or noise)
- ☒ Subjective rating (listening to sounds and judging, e.g., loudness, clarity, sound quality)
- ☐ Tests involving two tasks at the same time (dual-task paradigms)
- ☒ Questionnaires about device usability, appeal, acceptance, preference and performance
- ☐ Questionnaires about hearing handicap, tinnitus and/or attitudes towards hearing loss
- ☒ Completing a diary about your experience during a home trial

☐ You will also be asked to perform following activities while participating in the study:
- ☐ Memorizing items you hear or see on a screen
- ☐ Walking along a defined track

☐ Remote appointments will take place via video calls (i.e., Skype, MS Teams, interfaces for remote hearing aid fitting). These means may also be used to collect your information (i.e., demographic information) and to conduct tests remotely (i.e., subjective ratings, hearing tests).

☐ You will be recorded with ☐ cameras and/or ☐ microphones during your study participation.

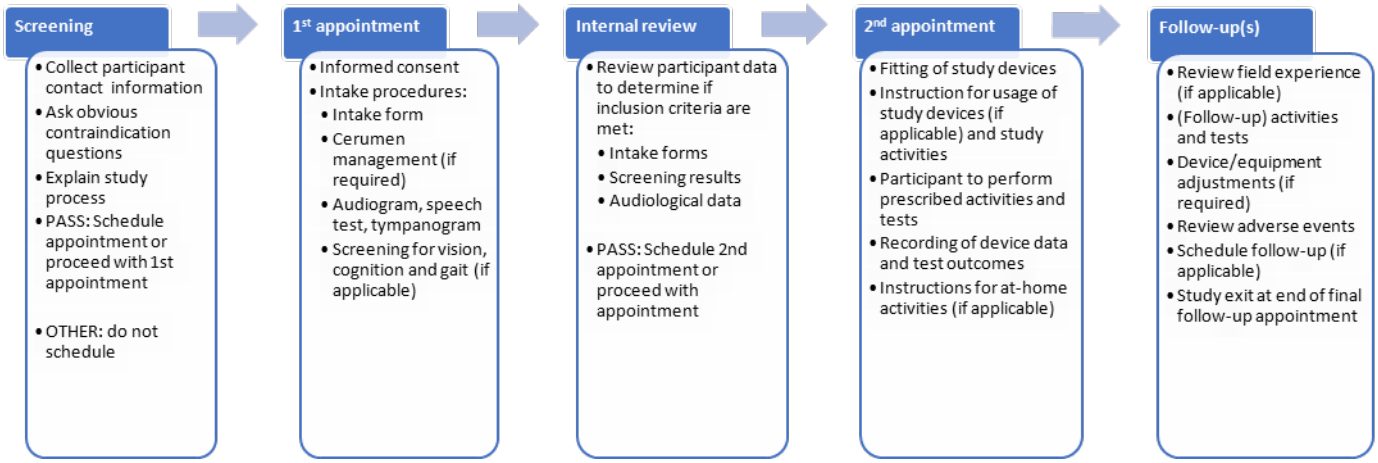
☐ You will receive study equipment for use at home not listed under devices, such as:
- ☐ Tablet
- ☐ Headphones
- ☐ Laptop
- ☐ Hearing aid fitting interface
- ☐ Smartphone

By doing this, researchers at Sonova will be able to evaluate and determine the performance, outcomes and benefits of the technology being tested. The research team can provide you with further information and answer any additional questions that you have regarding this study.

Any specific requirements regarding follow-up visits will be discussed with you prior to your enrollment in the study. Each test or task will be explained to you in all details before

commencing.

Study screening and participation will follow this flowchart:



What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: accurately report your health information so that the researchers can determine whether or not you are safe to participate in study activities, as well as determine which level of activity participation is right for you. You are also asked to always report your true opinions and impressions during tests and activities with no regards to whether they are positive or negative. Additionally, some subjects may be asked to complete at-home activities at the direction of the research team. Responses will be recorded by the researcher. The use of any supplied devices or equipment is restricted to study participants. At the end of the study, any devices or equipment will be returned to the researchers or properly disposed of as directed by the researchers.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include mild discomfort, pain or skin sensitivity from wearing the hearing aids or biometric sensors, discomfort, annoyance, or tinnitus from hearing aid use. Risks associated with activity participation may include: tripping or falling, choking during chewing activities, elevated heart rate blood pressure, or cardiovascular events in the case of unknown pre-existing health conditions. In case you feel any discomfort or stress, please let the researchers know immediately.

For research involving investigational devices, there may be side effects which are unknown at this time.

If you feel that you have been injured by participating in this research, please notify the study team. They will treat you or refer you to where you can obtain treatment. There are no plans to provide compensation for any injuries you experience while participating in this research.

Will it cost me money to take part in this research?

There is no cost to you to participate in this research.

Will I be compensated?

- ☒ You will receive $20/hour for your participation in study visits (in person or remotely). If you withdraw before completing a study session, then you will receive compensation pro-rated at $5/15 minutes.
- ☒ You will receive $40CAD for the completed diary (home trial only).

The non-financial benefits you may expect from the study are a greater understanding of research on hearing aid technology and the opportunity to contribute to scientific research. The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

Will being in this research benefit me?

Those with hearing loss may experience the benefit of improved hearing while using the devices. Participants with hearing impairment may experience improvements in their hearing during the study as a result of hearing instrument use. All hearing instruments and accessories will be returned at the end of the study, but a positive experience may educate participants about potential benefits from amplification.

By participating in this study, you will help clinicians, engineers and scientists develop new hearing technology. What other choices do I have besides taking part in this research?

This is not a treatment study**.** Your alternative is to not be in this study. Instead of being in this research, your choices may include visiting an audiologist or other hearing healthcare provider to have a hearing assessment and/or explore the option of amplification for improved hearing and communication.

What happens to the information collected for this research?

If you sign this form, you will be giving your permission for the collection, use and disclosure of your personal information for the purposes of this study.

If you decide to be in this study, the principal investigator and research team will collect information about you. This may include your name or initials, date of birth, gender, ethnic origin, medical history and health-related information such as results of laboratory tests, x-rays and physical examinations and medical records.

Data coded by your ID number only will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor in Canada and its headquarters in Switzerland
- People who work with the research sponsor
- The Research Ethics Board (REB) that reviewed this research

The information will be given to Health Canada. It may also be given to the U.S. Food and Drug Administration (FDA) and governmental agencies in other countries where the study device may be considered for approval. Information, including your medical records, which identifies you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by the sponsor;

Your data may be looked at and/or copied for research or regulatory purposes by:

- Health Canada;
- the FDA;
- governmental agencies in other countries; and
- WCG Institutional Review Board® (WCG IRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

We may publish the results of this research in a scholarly publication and/or reported in a scientific presentation. However, we will keep your name and other identifying information confidential.

Sonova Canada Inc. and its contractors or affiliates may process or host personal information using databases and IT systems located outside of Canada, including the United States, Switzerland and United Kingdom. For additional information on our privacy practices, please view our Privacy Policy at https://www.sonova.com/en/data-protection-statement

We protect your information from disclosure to others to the extent required by law (Personal Information Protection and Electronic Documents Act (PIPEDA) and the Freedom of Information and Protection of Privacy Act (FIPPA)). We will retain information collected in this study until we

have finished analyzing it and the data coded by number will be kept for five years after reports have been published. As soon as the purpose of the study is fulfilled or at any time upon your request, we will destroy your personal data. When it is destroyed, data will be shredded if it is on paper or erased if it is digital.

You have access rights to your information and the possibility to correct your information according to local law and procedures. You can discuss this with the research team. There is no expiration for your permission. You may take away your permission to collect, use and share information about you at any time by providing reasonable notice to the research team. If you do this, you will not be able to stay in this study. No new information about you will be gathered after that date. However, the information about you that has already been gathered may still be used and given to others as described in this form.

Who can answer my questions about this research?

If you have questions, concerns, or complaints at the time you are providing your consent, any time during the study or later, talk to the research team at the phone number listed above on the first page.

This research is being overseen by [a] Research Ethics Board (REB). An REB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289, researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest.
- Your health conditions change increasing your risk during participation in study experiments.
- The research is cancelled by the sponsor.
- You are unable to keep your scheduled appointments.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team by e-mail or telephone so that the investigator can cancel any future appointments and collect any study devices. The sponsor may still use your information collected prior to you leaving the study.

Can I tell anybody about my participation in this study?

Yes, you can tell anyone! But only that you participated in a hearing study at Sonova Innovation Centre Toronto and your participation is helping further develop hearing technology. You can actually invite them to participate in future studies as well. However, confidential information will be shared with you during your participation in this study, including ideas and information related to the products, features, and services offered or planned to be offered by Sonova. This information is sensitive and valuable to Sonova. It is therefore a requirement of your participation in this study that you agree not to make use of, disseminate or disclose this confidential information to any person, firm, corporation, social media groups, blogs, or articles of any kind. This restriction is waived if the information is, or later becomes generally available to the public. Initials: [ ]

Statement of Consent:

I have been informed by the investigator about the essence, significance and implications of this clinical study. I have read this Disclosure and Consent in its entirety. I have had the opportunity to discuss it with others and to ask questions. I was informed about the study plan and about my rights and obligations. If I provided an emergency contact, the research team may contact this person in case of emergency. I have received a copy of this Disclosure and Consent.

I have not waived any of my rights to legal recourse, including if I am harmed as a result of the research, by participating in this research.

_____ _____

Name and signature of adult participant capable of consent *Date*

Emergency contact name: **Telephone number:**

_____ _____

Name and signature of person obtaining consent *Date*

Optional: If you are interested in being contacted by Sonova Canada Inc. to learn more about future research opportunities in general, please sign below. We also ask for your permission to store your contact information, audiogram and your information on the study intake form in order to determine future studies that are a good fit for you. If you do not want to be contacted for future studies at any time, please let us know and your data will be deleted.

Name and signature of adult participant capable of consent	*Date*

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The researcher will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The research team.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:

- Governmental agencies in other countries,
- The institution where the research is being done,
- WCG Institutional Review Board® (WCGIRB®), the Research Ethics Board.

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2060.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by giving reasonable notice to the research team. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
While Sonova Innovation Centre Toronto complies with the Personal Information Protection & Electronic Documents Act and the Freedom of Information & Protection of Privacy Act, there is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Name and signature of participant capable of consent ***Date***