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DALHOUSIE UNIVERSITY

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Appendix 5: Consent Form

CONSENT FORM

[Secondary analysis of personal records]

Project Title

Investigation into increased sensorineural hearing loss in recovered individuals with diagnosed COVID-19 in Canada

Lead researcher

Patricia Van Roon, Dalhousie University, patricia.vanroon@dal.ca, 613-407-5482

Other researchers

Steve Aiken, Dalhousie University, steve.aiken@dal.ca, 902-494-1057 (Supervisor)
Hilmi Dajani, University of Ottawa, hdajani@site.uottawa.ca (Co-Supervisor)

Introduction

We invite you to take part in a research study conducted by Patricia Van Roon who is a PhD candidate at Dalhousie University. Taking part in the research or not is entirely your choice. There will be no impact on the services you receive if you decide not to participate in the research. The information below tells you about what is involved in the research, what you will be asked to do and about any benefit, risk, inconvenience or discomfort that you might experience. You should discuss any questions you have about this study with your clinician. Please ask as many questions as you like. If you have more questions later, please contact Patricia Van Roon.

Purpose and Outline of the Research Study

Researchers around the world are examining the impact of COVID-19. Recent studies show the virus can affect the senses such as the loss of smell and the loss of taste. We want to check if the virus can also affect hearing by analyzing your pre- and post-virus hearing tests. You will not need to perform any additional hearing tests other than the tests the clinician normally performs when you visit the clinic. We are recruiting clients with a confirmed diagnosis of COVID-19 from a hospital in Canada who have currently recovered. We will ask you to answer two questions regarding the severity of the virus. We also ask the clinician, with your permission, to transfer your pre-virus hearing tests over the past two years (2018, 2019) as well as your post-virus hearing tests.

Who Will be Included in the Research Study

Adults over 18 years of age who have recovered from a COVID-19 infection can participate in the study if they

1. Have a non-fluctuating sensorineural hearing loss, and
2. Have regular hearing tests for two years before a COVID-19 infection and one or two

hearing tests after the COVID-19 infection.

How Will Data be Collected and Used

The researcher will send a request to the clinician. The clinician will select those eligible according to the above criteria, who have granted consent. The clinician will securely transfer the records for the two previous years (2018, 2019) and the current hearing test. The clinician will prepare a duplicate file with your name removed. When the researcher receives the document, she will assign a unique study ID. The research team will only see the duplicate file. Your hearing tests will be compared from before and after the virus exposure.

Possible Benefits and Risks

Participating in the study will not benefit you directly. We hope to learn things that will benefit others. Your clinician will address any changes in your hearing.

All clinic staff are committed to maintaining confidentiality. The clinician will not use your name or identifying information if the researcher needs to ask the clinician a question about the record.

How information will be protected:

Your clinician is the only person who will know of your participation in this research project.

Confidentiality

The research team keeps all information gathered about you confidential. Only the research team at Dalhousie University will have access to the anonymized information. The clinician transfers the consent form with your name in a separate password-protected zip file. We will use a participant ID (not your name or initials) in our written and computer records so that the research data we have about you contains no identifying information. During the study, the researcher will securely store all electronic records in an encrypted file on the researcher's password-protected computer. The researcher will not store paper records of the consent form. The researcher will destroy the consent forms at the end of the study.

We will describe and share our findings in the researcher's thesis, presentations, public media, journal articles, etc. We will report group results and anonymized grouped individual results. Our reports will not be able to identify you in any way.

It is possible that a journal will ask the research to post your anonymized data on a publicly available repository to advance the research of COVID-19 as part of the publication process.

Data retention

The project supervisor retains your data indefinitely. However, the researcher will securely destroy the consent forms when the researcher completes the study.

Study Withdrawal

If you do not wish to include your data, please let your clinician know. You may withdraw up to one week after participation. After that time, the researcher incorporates the data into the group analysis and withdrawal becomes impossible. If you withdraw prior to that time, your data and consent will be securely electronically shredded using the Bitdefender antivirus file shredder. Withdrawal will in no way affect your treatment at the clinic, your place of employment, or the participating universities.

How to Obtain Results

If the clinician would like a copy of our results, we will provide the clinician with a short description of group results when the study is completed. The researcher will show group results as either a group average or a group of anonymous individual results from several clinics across Canada. The clinician can relay the results to their client(s) when the researcher completes the study in 2020–2021.

Questions

Please consult with your clinician about any questions you may have about this research to maintain your anonymity. Your clinician will contact the researcher about any unanswered questions.

If you have any ethical concerns about your participation in this research, you may also contact Research Ethics, Dalhousie University at (902) 494-1462, or email: ethics@dal.ca. Please reference REB file # 2020-5185 when you call.

Signature Page

Project Title

Investigation into increased sensorineural hearing loss in recovered individuals with diagnosed symptomatic COVID-19 in Canada

Lead Researcher

Patricia Van Roon, Dalhousie University, patricia.vanroon@dal.ca, 613-407-5482

I have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered to my satisfaction. I understand that I am giving permission to allow researchers to use my anonymized hearing tests for a study about hearing loss and the severity of COVID-19. I understand that I will need to complete a short questionnaire about the severity of my COVID-19. I understand that no one will know whether my data were included in the study, and that participating or not will have no repercussions for me at my clinic, my place of employment, or at participating universities. Once the clinician anonymizes my records, there will be no way for me to withdraw them.

I agree that my hearing tests can be used for this study. I agree that the researchers can use my responses to the COVID-19 severity questionnaire for this study.

_____
Name

_____ _____
Signature Date

Optional

I am interested in participating in future studies ☐ Yes ☐ No

I agree to allow the researcher to upload my anonymized data to a public repository designated by a publisher for the purposes of advancing COVID-19 research. ☐ Yes ☐ No

_____
Name

_____ _____
Signature Date

Please contact your clinician if you would like to be sent a summary of the study results