

Supplemental File 1
Interview Consent Form - Example (Phase 1)



Information and Agreement Form to Participate in Study

Title of Study: Long COVID and Episodic Disability: Advancing the Conceptualization, Measurement and Knowledge of Episodic Disability with people living with Long COVID

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Research Team

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Community Collaborators

Long COVID Support, UK - Margaret O'Hara
Long Haulers Support Group of Canada - Susie Goulding
Patient-Led Research Collaborative - Hannah Davis, Lisa McCorkell, Hannah Wei
Long COVID Physio - Catherine Thompson, Darren Brown, Kelly O'Brien
Long COVID Ireland – Niamh Roche, Ruth Stokes
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INTRODUCTION

You are being asked to take part in a research study about disability experienced by adults living with Long COVID. The purpose of this study is to enhance understanding of the experiences of adults living with Long COVID, and to develop and assess a new questionnaire that can measure the types of disability experienced by people living with Long COVID, such as fatigue, pain, and challenges with day-to-day activities. Your participation will help to inform researchers on the use of this questionnaire and its ability to help refer people living with Long COVID to services and improved goal setting and communication between patients and their health providers. This research is a collaboration between researchers in Canada, United Kingdom (UK), United States (US), and Ireland.

In order to decide whether you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. If you have any questions after reviewing this information letter and consent form, please do not hesitate to ask. If you understand the parts of the study and want to participate, you will be asked to sign a consent form (or verbally agree to participate and your consent will be documented by the study coordinator on the consent form).

WHY IS THIS RESEARCH BEING DONE?

As the prevalence of Long COVID increases, more individuals are living with ongoing physical, mental and social health challenges after COVID-19 infection, known as **disability**. Questionnaires designed to capture this disability are important for health providers to understand the disability experienced so that they can provide care. Our research team has previously developed questionnaires in the context of adults living with HIV in Canada, US, Ireland and UK. We hope to build on this work and apply lessons learned in other chronic and episodic conditions to understand and conceptualize disability experienced among adults living with Long COVID.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to gain a better understanding of the disability experiences among people living with Long COVID, to develop the Episodic Disability Questionnaire (EDQ), and assess how well this questionnaire can measure disability in people living with Long COVID.

WHO IS CONDUCTING THIS STUDY?

The team conducting this study includes people living with Long COVID, people affiliated with COVID support networks, and researchers and clinicians working in COVID-19 care in Canada, US, Ireland, and UK. This study will involve participants living with Long COVID in all four countries. University of Toronto (Canada) is the primary site of the study.

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WHAT IS INVOLVED BY TAKING PART IN THIS STUDY?

One-on-One Interview: If you agree to take part in this study, you will be asked to participate in an interview approximately 60 minutes in duration whereby you will be asked questions about your health-related challenges living with Long COVID. The interview will include questions about your physical, mental, emotional, and cognitive challenges, how these challenges might fluctuate over time, and what triggers or helps your challenges improve. Lastly, you will be asked about any strategies or services you use to deal with the challenges you face.

The interview discussion will be used to develop this new measure of disability for adults living with Long COVID. A member of the research team will facilitate the interview through Zoom. The interview will be audio-recorded (using an audio recorder) and later typed out word for word with any names or personal identifiers removed.

Demographic Questionnaire: At the end of the interview, you will be asked to complete an web-based demographic questionnaire, which will include questions about various factors, such as sex, gender, race, health conditions you might be living with in addition to Long COVID, past hospitalizations, timing of acute COVID-19 diagnosis, and symptom onset. This questionnaire will take approximately 10 minutes to complete.

The interview is the first phase of this research study. There is a second phase of this research which involves completion of additional questionnaires. If you are interested in this second phase as well, please indicate your interest when you complete your consent form.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Computer files containing the interview files and questionnaire responses will be stored on a secure server hosted by the University of Toronto. Consent forms will be uploaded and stored on the secure server at the University of Toronto (or respective site in the country of participation). Only researchers and advisors directly involved with the study will be able to access these files.

Audio files from the interviews will immediately be transferred from the recording device to a secure, online storage site with password protection. The files on the recorded device will then be deleted. Audio files will be deleted from the online storage site after the study is published, and all paper and electronic files will be destroyed ten years after the study is completed.

The one-on-one interview will take place virtually through Zoom. Any information you provide throughout your participation in the study, including contact information, recordings from the interview and questionnaire responses will be kept strictly confidential and only be made available to the research team and members of the University of Toronto Research Ethics Board who have reviewed the study. No information that would identify you (such as your name) will be recorded on any of our documents. For example, you will be assigned a specific numerical code that will be used to refer to you instead of your name. Only the researchers and investigators will have access to the meaning of this code and it will not be shared with anyone else. We will not include any personal information such as your name that could identify you in any of the publications or presentations related to this study.

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WHAT ARE THE POSSIBLE RISKS?

There are no obvious risks if you decide to be in this study. There may be unforeseen risks. It is possible that you may find some questions in the one-on-one interview personal or uncomfortable to answer. You may choose not to answer questions for any reason and you may stop taking part in the one-on-one interview at any time. Additionally, if you feel you would benefit from having the interview broken up into multiple sessions, this can be arranged with the interviewer. If you become upset during the one-on-one interview or when filling out the questionnaire, the researchers will encourage you to follow up with your health care professional (e.g. physician), qualified counselor, or services at the relevant community site/network, and can provide you with the contact information for support services relevant to your area. Further, the research team will follow up with all participants via email after the interview and will include the contact information for the Principal Investigator / site lead and the relevant community collaborator network should the participant require these services. Choosing to withdraw from the study will not compromise any care you receive through any COVID-19 support networks/services.

WHAT ARE THE POSSIBLE BENEFITS?

You may or may not benefit from participating in this research study. Taking part in this study will not give you any direct health benefits. However, knowledge gained from this study may help to advance the field of rehabilitation in the context of Long COVID. Results from this study may directly help to develop a disability questionnaire and advance knowledge about disability that adults living with Long COVID experience.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will not be paid to take part in this research study, but you will be given a \$30 CAD dollar gift card as a token of appreciation to thank you for your participation in completing the one-on-one interview and questionnaire. If you choose to withdraw from the study during the interview, you will still receive the gift card.

WHAT WILL HAPPEN TO THE INFORMATION FROM THIS STUDY?

The researchers will submit a manuscript for open-access publication as well as communicate the knowledge gained from this study to researchers, health-care providers, community-based organizations and policy makers. Knowledge translation updates will be provided in the form of presentations, slides, fact sheets and social media. This information will also be presented at community organizations and clinics encouraging practical application of the results. Fact sheets of the results will be distributed by email if requested and as handouts. If you are interested in receiving a copy of the fact sheets and publications from the study investigators, you can contact Kelly O'Brien at kelly.obrien@utoronto.ca. All data/publications related to the study will be open access (available to anyone) as a condition of the study's funding in accordance with the joint statement on sharing research data and findings relevant to the novel coronavirus outbreak. Any available data will be in aggregate form, without any personal identifiers to protect the anonymity of participants. A summary of the study results and publications will be openly available on the Long COVID Physio website: <https://longcovid.physio>.

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IF I HAVE ANY QUESTIONS OR CONCERNS, WHOM CAN I CONTACT?

If you have any questions about the research study, please contact Kelly O'Brien (Principal Investigator) at kelly.obrien@utoronto.ca or (416) 946-3935 or Brittany Torres (Research Coordinator) at brittany.torres@utoronto.ca or (416) 946-3935.

If you have any questions regarding your rights as a research participant please contact the Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

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CONSENT TO PARTICIPATE



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I have read and understood all of the above. Signing this form does not waive my legal rights or relieve the investigator or sponsors from their legal and professional responsibilities.

I agree and consent to participating in completing the self-reported questionnaire and one-on-one interview.

By signing or giving verbal consent below I am agreeing that:

- I understand the information provided for the above study.
- I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.
- I understand that my participation is voluntary and that I am free to stop the study at any time without punishment.
- I understand that the data collected during the study may be looked at by responsible individuals from the research team, or the regulatory authorities where it is relevant. I give permission to these individuals to have access to the information I provided.
- I agree to participate in the above study.
- For the interview, I agree to be audio recorded.
- I have been provided with a copy of the consent form.

Provision of written consent

Participant's Name (please print)

Participant's Signature

Date

Provision of verbal consent

Witness' Name (please print)

Witness' Signature

Date

I am willing to be contacted about **future phases of the study** by email or phone.

- Yes, Contact: _____
- No