

e-Mental Health Consent

This document is meant to illustrate our consent agreement. If you are participating in the e-Mental Health project, the consent document will be sent to you electronically to complete. Do not fill out this document.

UNIVERSITY OF CALGARY - CONSENT TO PARTICIPATE IN RESEARCH

TITLE: e-Mental Health for Youth and Young Adults in Alberta

SPONSOR: University of Calgary

FUNDER: Alberta Innovates – Health Solutions, Alberta Childrens' Hospital Foundation

INVESTIGATORS: Dr. David Johnson, MD, Phone: 403-955-2640 & Dr. Gina Dimitropoulos, PhD, MSW, RSW, RMFT, Phone: 403-220-7332

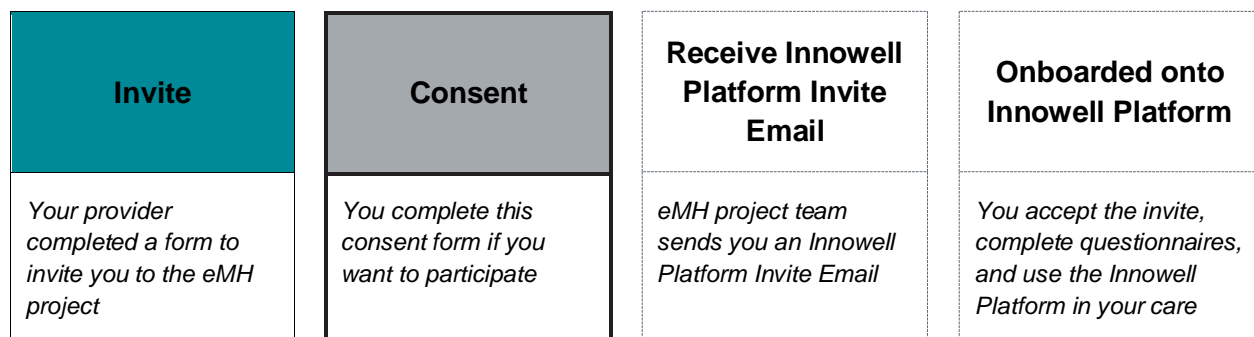
CONTACT: emh@ahs.ca

Introduction

Dr. David Johnson, Dr. Dimitropoulos, and associates from the University of Calgary are conducting a research study.

This consent form is only part of the process of informed consent. It will give you the basic idea of what the research is about and what your participation will involve. If you would like more information please contact us at emh@ahs.ca. Please take the time to read and understand this information. You will receive a copy of this form for your records.

Your mental health provider invited you to participate in this study and thinks you may benefit from accessing an electronic mental health (eMH) platform and resources. Your participation in this research study is voluntary and depends on you completing this consent form. The onboarding process is shown below:



Why is this study being done?

- We want to improve mental health care for youth and young adults in Alberta
- We are evaluating whether the Innowell Platform, an electronic mental health platform, improves care and outcomes for clients who use it.

How many people will take part in this study?

- Up to 1000 people will take part in using the Innowell platform across Alberta. All participants will take part in this study through the University of Calgary.

What will happen if I take part in this study?

If you participate in this study, you will be asked to do the following:

Participate in care

- You will access mental health support at your site as you would for treatment as usual

Use the Innowell Platform

- Provide demographic information (age, sex, gender, etc.) and your healthcare number
- Regularly complete online questionnaires about your mental health, including anxiety, depression, and substance use, to track your progress over time and help with your treatment
- The initial assessment should take about 45 minutes and follow-up questionnaires should take 10-15 minutes to complete. Your provider will ask you to complete these questionnaires on a regular basis to track progress and inform treatment planning.
- Use apps, e-tools, and other care options to help with your treatment

Provide past health care use information

- Give permission for researchers to access your past health records to understand what mental health services you have accessed. This will help the research team to understand whether using Innowell reduces future mental health services use for clients.
- Researchers will not view your overall health record, and will only receive information about mental health services accessed. Records will be de-identified as part of the analysis so it is only displayed in an anonymous way, as described below.

Provide feedback (optional)

- Depending on your preferences, you may be contacted to provide feedback on your experience using the platform (surveys, focus groups, etc.). This will help us understand how to improve the platform for future use.

What will happen when I am finished using the eMH platform?

- You will be discharged from the Innowell Platform.
- You will no longer be able to complete the online questionnaires but you will be able to view your Innowell Platform data and continue to access any apps you previously used.
- You can continue to access any mental health services at your site or in your community.

How long will I be in the study?

- Participation time will vary and is related to your provider's clinical judgement, your progress, and how long you continue to access mental health treatment with this provider and/or at this site
- You are free to choose to stop participating in using the eMH platform at any time

Are there any potential risks or discomforts that I can expect from this study?

- The questionnaires may ask questions about your mental health and substance use that are sensitive in nature. Your provider may support you through this aspect and you are welcome to take breaks as needed when completing the questionnaires.

What are the potential benefits if I participate?

- The Innowell Platform is rooted in research evidence showing improved care for clients who use the platform. We are assessing what this looks like when applied to clients in Alberta.
- Using regular assessments to track progress and change treatment has been shown to improve care, and you may experience this.
- The Innowell Platform includes over 60 apps and e-tools that are free and evidence-based, which may also benefit your care
- As with any treatment, there is no guarantee you will benefit. This is part of what this research study is looking at.
- Information from this study will inform future use of eMH in Alberta, which could positively impact mental health care in the province.

What other choices do I have if I choose not to participate?

- If you choose not to participate, there is no penalty to you and your decision will not affect the standard of care you receive
- You will still access mental health services with this provider and/or at this site
- We will inform your provider that you do not consent to participate and you will continue to receive treatment as usual from your provider
- You will not have access to the Innowell Platform

Can I stop being in the study?

- Yes, you may stop at any time. Please contact your provider or emh@ahs.ca if you'd like to withdraw from using the Innowell Platform.

- If you decide to stop being in the study, the data collected about you up to that point will remain part of the study unless you choose to withdraw your study data. If you want to withdraw your study data, please contact your provider or emh@ahs.ca within 30 days after withdrawal from the study.
- The eMH project will delete information at your request, prior to data being moved to Alberta Health Services in 2024. Data that has already been de-identified and moved cannot be withdrawn.

Will I be paid for participating, or do I have to pay for anything?

- No. You will not be paid for your participation in this research study. You will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.

Will information about me and my participation be kept confidential?

- The researchers will do their best to make sure that your private information is kept confidential.
- Data will be stored on a secure, encrypted, and password-protected servers. Only authorized individuals will have access to it.
- Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy. We are also limited to the extent permitted by law (for example, child abuse or neglect must be reported, risk of harm to yourself or others must be disclosed).
- The research team will handle data according the Data Management Plan as outlined below for the following scenarios:
 - **To inform your healthcare**
 - While you are on the Innowell Platform, your provider and healthcare team will have access to the information you provide
 - If the Innowell Platform rates you at high risk of harm, your provider and healthcare team will be notified automatically by the Innowell Platform. In some instances with increased risk, the research team may also be alerted to ensure you are connected with appropriate care. This is rare.
 - **To evaluate the eMH project**
 - When it is time to evaluate the information collected from the study, we will only use de-identified data. This means that all data that could identify who you are, such as your name or email, will be removed.
 - To de-identify your data, any identifiable information about you will be replaced with a code. A master list linking the code and your identifiable information will be kept separate from the research data to help preserve confidentiality

How long will study data be kept?

- Information will be stored within the Innowell Platform until the data is transferred to Alberta Health Services in 2024. At that time, AHS will provide instructions to destroy all identifiable data.
- University policy requires that we keep your information for a period of at least five years after final publication of the study results.
- If you consent to your research data being used in future mental health research (see below), it will be stored indefinitely. Any future use of this research data is required to undergo review by a Research Ethics Board.

Researcher conflicts of interest

- No members of the study team have a personal or financial conflict of interest with the study.

Who can I contact if I have questions about this study?

The Research Team:

- You may contact the eMH project team (emh@ahs.ca), Dr. David Johnson (403-955-2640), or Dr. Gina Dimitropoulos (403-220-7332) with any questions or concerns about the research or your participation in the study.

Conjoint Health Research Ethics Board (CHREB):

- If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

How can I find out about the study results?

- Study results will be available after analysis upon request.

What are my rights if I take part in the study?

- Taking part in this study is your choice.
- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the standard medical care you receive.
- If you decide to take part, you may leave the study at any time.

How do I indicate my agreement to participate?

Your signature indicates that you:

- Understand, to your satisfaction, the information regarding your participation in the research project
- Agree to participate

In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities

Do you consent that your de-identified research data may be kept for use in future research to learn about, prevent or treat other health-related problems?

Ethics ID: REB21-0343

Study Title: e-Mental Health for Youth and Young Adults in Alberta

PI: Dr. David Johnson

Version 4.0: May 12, 2023

If you consent to be involved in this study, you will also be asked about the following:

Use of data for future research

In some cases, research data may be kept for use in future research to learn about, prevent, or treat mental health-related problems in studies that have not yet been determined. It is your choice whether or not to let researchers share your data for research in the future. If you say “yes,” you can change your mind later, but your data might still be used if they have already been shared. In this scenario, future research will first receive ethical approval. Dr. David Johnston and Dr. Gina Dimitropoulos will remain the data custodians for your research data at the University of Calgary, and will be involved in any future research studies that use your research data.

Do you consent that your de-identified research data may be kept for use in future research to learn about, prevent or treat other health-related problems?

Contact for future research

University of Calgary researchers may contact me in the future to ask me to take part in other research studies.

Personal information

What is your postal code?

What is your Personal Health Number (PHN) or Unique Lifetime Identifier (ULI) number?
Please locate your Personal Health Number (PHN) on your Alberta Health Care Card.

How old are you today?

If you are ages 15-17, you will be asked to answer please answer these additional questions.

What is the purpose of this project?

- To provide group therapy online
- To evaluate an e-Mental Health project
- To design new smartphone apps

Do you have to be in this project if you don't want to?

- Yes
- No

If you decide to withdraw from this study, will it negatively impact any current or future mental health care that you receive?

- Yes
- No

What are three things that will happen if you participate in this project?

- Demographic questions, mental health questions, answers can be viewed by the person who referred you
- Online group therapy, mental health questions, indicial interview
- Demographic questions, online journaling, referral to new physician