Clinical Trial
Consent Form: Patients

STUDY TITLE: **Evaluation of a Mental Health Physician Support Program in Nova Scotia: Impact on Patient Outcomes and Stigmatization**

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STUDY SPONSOR: Opening Minds, Mental Health Commission of Canada

1. Introduction

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please ask the study staff or the principal investigator to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

The researchers will:

- Discuss the study with you
- Answer your questions
- Keep confidential any information which could identify you personally
- Be available during the study to deal with problems and answer questions

You are being asked to consider participating in this study because you are a patient of a physician who has agreed to participate in the training program, you are suffering from depression, and you have given permission to your physician for us to contact you.

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

2. What is the purpose of this study?

The purpose of this study is to examine and compare the effects of a training program to help physicians enhance their skills and confidence in diagnosing and treating mental health problems.

3. What Is Being Tested?

We will be testing a mental health training program for depression by primary care physicians. For this study, patients, medical office staff and physicians are taking part. We will be collecting different information from all groups by way of interviews and questionnaires. As a patient, if you agree to participate, we will be collecting from you:

1- Month and year, gender, marital status, ethnic group, country of birth, mother tongue, highest completed level of education, living situation, employment, and income
2- A measure of depression symptoms; Patient Health Questionnaire- 9 (PHQ-9)
3- A measure of your functioning at work: Lam Employment and Productivity Scale (LEAP)
4- A measure of your general functioning; the Sheehan Disability scale

5- antidepressant medication you are taking
6- A quality of Life Scale; The Short Form-36 (SF-36)
7- Satisfaction of the care you received

In total, there will be 5 telephone interviews. These will occur at the start, 1, 2, 3 and 6 months after we get your consent. There are no experimental drugs or devices involved in this study.

4. How Long Will I Be In The Study?

You will be involved in the study for approximately 6 months.

5. How Many People Will Take Part In This Study?

This study is taking place only in Nova Scotia. It is expected that approximately 200 patients will participate in the study. Approximately 110 primary care physicians and 110 medical office assistants are also participants in this study.

6. How Is The Study Being Done?

Half of the doctors with their MOA have been assigned by chance to the training program, the other half will manage patients with depression as they usually do. Your physician has been asked to identify 3 consecutive patients with depression to take part of this study. As a patient, if you agree to participate, you will become part of the same group as your physician and your physician will manage your depression. You will be asked to complete questionnaires as per section (3). This will take approximately 30-45 minutes. You will be contacted by the study coordinator by telephone to collect information from questionnaires you have completed. Because this research is a randomized control study, the one thing you will not know is which group your family doctor will be assigned to.

Your physician will complete questionnaires to test their comfort and satisfaction of the strategies, and their attitudes associated with mental illness. Medical office assistants will complete a similar set of questionnaires similar to the physician questionnaires, testing, stigma (or negative attitude), comfort and satisfaction. Stigma (or negative attitude) is a key component of the program being evaluated.

7. What Will Happen If I Take Part In This Study?

Once you consent to participate, you will be assigned a number specific only to you. The research coordinator will collect information as per section (3) by telephone interview at 5 separate time points over this period; at the beginning of the study, 1,2,3, and at 6 months (end of study). We ask that you not reveal the name of your physician to the study coordinator.

8. Are There Risks To The Study?

There are risks with this, or any study. To give you the most complete information available, we have listed possible risks that may occur. Please also be aware that there may be risks in participating in this study that we do not know about yet.

You may find the interviews and questionnaires you receive during the course of the study upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer those questions you find too distressing. You can withdraw from the study at any time without affecting your care.

9. Are There Other Choices?

You do not have to be in this trial to get care for your problems. You can decline to participate in the study and your physician will still treat you for your depression and therefore will not deviate from the standard of care.

10. What Happens at the End of the Study?

At the end of the study, research results will be compiled by the research team. The project is sponsored by the Mental Health Commission of Canada. Data will be stored in a secure location in Calgary, Alberta by the Commission. Your information will also be stored by the Patient Research Centre at Capital Health. If you are interested in learning about the results of the study, these will be made available to you when ready.

11. What Are My Responsibilities?

As a study participant you will be expected to:

- Participate in 5 confidential interviews throughout the course of the study
- Not reveal the name of your physician to the research coordinator
- Follow the treatment plan provided to you by your physician
- Let the research coordinator know if anything about your contact information changes over the course of the study.
- Report any problems that you experience that you think might be related to participating in the study.

12. Can I Be Taken Out Of The Study Without My Consent?

The Principal Investigator may withdraw a participant at any point. As an example the PI may withdraw a patient who poses a risk to themselves or others. The study sponsor, the Capital Health Research Ethics Board, Health Canada or the Principal Investigator have the right to stop recruitment or cancel the study at any time.

13. What About New Information?

It is possible that new information may become available while you are in the study about some new treatment for your condition. You will be told about any other new information that might affect your health, welfare, or willingness to stay in the study and will be asked whether you wish to continue taking part in the study or not.

14. Will It Cost Me Anything?

Compensation

You will not be paid to be in the study. There is no charge for the study. You may have to pay for drugs such as those prescribed by your physician.

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate in the study. In no way does this waive your legal rights nor release the Principal Investigator, the research team, the study sponsor or involved institutions from their legal and professional responsibilities.

15. What About My Privacy and Confidentiality?

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. The principal investigator will have the master list linking participant names to their respective numbers. This list will be kept in a secure locked cabinet under the supervision of the principal investigator. No identifying information (such as your name) will be sent outside of this health care facility. If the results of this study are presented to the public, nobody will be able to tell that you were in the study.

However, complete privacy cannot be guaranteed. For example, the investigator may be required by law to allow access to research records. A copy of this consent form will be put in your health record.
When you sign this consent form, you give us permission to:

- Collect information from you
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety while participating in this research

Access to Records

Other people, during visits to this health care facility, may need to look at the study records. These people might include;

- People and companies working for and with the sponsor inside and outside Canada
- The Research Ethics Board and people working for or with the Research Ethics Board

Use of Your Study Information

The research team will collect and use only the information they need to judge the safety and usefulness of the training program.

You also allow the collection, reporting and transfer of your anonymous personal study information and data from the study to:

- The sponsor and companies working for and with the sponsor; and
- Regulatory authorities within and outside Canada

The sponsor and companies working for and with the sponsor will use the information collected about you during the study, only for scientific research and/or drug development purposes.

The Research Ethics Board may also contact you personally for quality assurance purposes.

Your Access to Records

You may ask the study doctor to see the information that has been collected about you. You may ask to make corrections to this information by talking with a member of the research team.

16. Declaration of Financial Interest

The sponsor is reimbursing the Principal Investigator and/or the Principal Investigator's institution to conduct this study. The amount of payment is sufficient to cover the costs of conducting the study.

17. What About Questions or Problems?

For further information about the study call **Dr. Bianca Horner.** Dr. Horner is in charge of this study at Dalhousie University (she is the "Local Principal Investigator"). Dr. Horner's work telephone number is (902) 473-563. If you can't reach the Principal

Investigator, please refer to the attached Research Team Contact Page for a full list of the people you can contact for further information about the study.

18. What Are My Rights?

After you have signed this consent form you will be given a copy.

If you have any questions about your rights as a research participant, contact the **Patient Representative** at **(902) 473-2133**.

In the next part you will be asked if you agree (consent) to join this study. If the answer is "yes", you will need to sign the form.

19. Consent Form Signature Page

I have reviewed all of the information in this consent form related to the trial called:

Evaluation of a Mental Health Physician Support Program in Nova Scotia: Impact on Patient Outcomes and Stigmatization

I have been given the opportunity to discuss this study All of my questions have been answered to my satisfaction.

I agree that my personal health and study information may be used as described in this consent form.

This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time without affecting my future care..

_____	_____	____ / _____ / ___
Signature of Participant	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Witness to Participant's Signature	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Investigator	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Person Conducting Consent Discussion	Name (Printed)	Year Month Day*

Note: Please fill in the dates personally

I Will Be Given A Signed Copy Of This Consent Form

Thank you for your time and patience!