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**Letter of Information and Consent**

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| **Project Title**  | The Impact of a Virtual-Based Monitoring Program on Glycemic Control for Patients with Diabetes: A Pilot Randomized Controlled Trial |
| **Document Title**  | Letter of Information and Consent - Patient |
| **Principal Investigator**  | Krista Smith, RD, Lennox and Addington County General Hospital, ksmith@lacgh.napanee.on.ca, 613-354-3301 x921 |
| **Additional Research Staff** |  |

1. **Invitation to Participate**

You are being invited to participate in this research study about the use of a virtual-based monitoring program (VBMP) to help you self-manage your diabetes because you are a member of the Diabetes Education Program at the Lennox and Addington County General Hospital and taking insulin.

1. **Why is this study being done?**

The purpose of this study is to determine if the use of a VBMP can improve your blood sugar control. The use of VBMP’s have been increasing and studies have shown improvements in blood sugar control, however very few studies have included a long term follow up after the use of the program.

1. **How long will you be in this study?**

It is expected that you will be in the study for 15 months. Depending on which group you get randomly assigned to, you will either have multiple short virtual meetings with your diabetes educator (quantity of meetings varies between participants) for 3 months and then in-person meetings every 3 months for another 12 months with your diabetes educator, or just the in-person meetings every 3 months for 15 months.

1. **What are the study procedures?**

If you agree to participate, you will be randomly assigned to the either the VBMP group or the standard of care (SOC) group. If you are randomly assigned to the virtual-based monitoring program you will be given a tablet with internet access to use and you will be in this group for 3 months, then after the 3 months you will move to the SOC group for another 12 months. If you are randomly assigned to the SOC group you will be in that group for the full 15 months. Before the study begins, all participants will fill out a questionnaire to assess levels of emotional distress. This same questionnaire will be repeated at month 3, 6, 9 and 15. Blood work will also be taken at these times to assess A1c levels (a biomarker reflecting your average blood sugar control over 2-3 months). If you are assigned to the VBMP group it is expected to complete at least 2 educational components each month over the course of 3 months and after the 3 months have passed you will fill out a satisfaction survey.

1. **What are the risks and harms of participating in this study?**

Considering this study will involve the collection of a blood sample, there will be a small risk of discomfort, bleeding or bruising from the blood drawing. Let staff know if you have a history of light-headedness, sweating, nausea and/or fainting when you have blood drawn.

1. **What are the benefits of participating in this study?**

The possible benefits to you include an improvement in blood glucose control, increased knowledge of diabetes and diabetes-related complications, and improvements in the ability to self-manage diabetes and the related complications. The possible benefits to society may be decreased health care cost

1. **Can participants choose to leave the study?**

If you decide to withdraw from the study, you will return to SOC and your information/results will not be used for analysis of the study.

1. **How will participants information be kept confidential?**

While we do our best to protect your information there is no guarantee that we will be able to do so. If data is collected during the project which may be required to report by law we have a duty to report. The researcher will keep any personal information about you in a secure and confidential location for a minimum of 10 years as required by the Public Hospitals Act. A list linking your study number with your name will be kept by the researcher in a secure place, separate from your study file. If the results of the study are published, your name will not be used.

1. **Are participants compensated to be in this study?**

You will not be compensated for your participation in this research.

1. **What are the rights of participants?**

Your participation in this study is voluntary. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time. If you choose not to participate or to leave the study at any time it will have no effect on your care.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

You do not waive any legal right by signing this consent form

1. **Whom do participants contact for questions?**

If you have questions about this research study please contact Krista Smith, RD, Lennox and Addington County General Hospital, ksmith@lacgh.napanee.on.ca, 613-354-3301 x921

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Research Officer at Brescia: Dr. Aaron Cecala, acecala@uwo.ca, 519-432-8353 x28044

**This letter is yours to keep for future reference.**