Joslin Diabetes Center

Committee on Human Studies

Informed Consent & Authorization Form

Participant's Name: _____

Participant's Status: ☐ **Joslin Patient** ☐ **Non-Joslin Patient** ☐ **Employee**

Principal Investigator: Osama Hamdy, MD

Co-Investigator(s): Elena Toschi, MD; Astrid Atakov Castillo, BA; Owen Henn, BA; Shaheen Tomah, MD; Taha Elseaidy, BS; Sahar Ashrafzadeh, BA; Khaled Alsibai, MD; Adham Mottalib, MD; Noor Mahmoud, MD

Study Title: Evaluation of use and patient satisfaction of hybrid closed-loop Medtronic 670G in real-world clinical settings: Prospective Multistage Surveys

Study Sponsor: Joslin Diabetes Center Funds

Study Contact: Sahar Ashrafzadeh (617) 309-4131; Taha Elseaidy (617) 309-4145
Osama Hamdy (617) 309-2726

This is a long and important document. This document describes a research study and explains how your medical information will be used and/or disclosed for the purposes of this research study, if you choose to participate.

You should take the time to read this document carefully. If you choose, you may take a copy of this document to discuss with your physician, legal counsel, family member or any one else you would like before signing it.

This document may contain information or words that are difficult to understand. It is very important that you ask the study investigator or a member of the study staff to explain any words or information that you do not understand.

Your participation in this research study is completely voluntary. If you agree to participate in this study, you will be asked to sign this form to show your consent to participate and your authorization for the use and/or disclosure of your medical information.

Do not sign this document unless you are comfortable with your decisions regarding both your consent to participate in this research study and your authorization for the use and/or disclosure of your medical information for this research study.

APPROVED BY THE
JOSLIN DIABETES CENTER
COMMITTEE ON HUMAN STUDIES
Do Not Use After
AUGUST 17, 2018

Participant's Initials: _____

Purpose of Study

You are being asked to participate in this study because you have type 1 diabetes and you are upgrading your current insulin delivery system and continuous glucose monitor to the new MiniMed 670G with SmartGuard™ Technology and the Guardian® Sensor 3.

The primary purpose of this observational study is to evaluate the use of this new technology the hybrid close-loop 670G pump.

This study will involve 75 patients at the Joslin Diabetes Center.

This study is being supported by Dr. Osama Hamdy's research funds from Joslin Diabetes Center.

Study Procedures

This study will last 1 year (52 weeks) and includes 3 visits to Joslin Diabetes Center.

All study visits will be combined with regularly scheduled clinic visits, during the pump upgrading process and follow up with your Joslin physician and/or educator.

For all study visits the study staff will collect:

- Your insulin, blood glucose and CGM information, the information will be downloaded either by clinic personnel or by the study staff. If the study staff obtains this information, the information obtained from the devices will be shared with your diabetes educator or Joslin physician for review as per clinical plan. If this information is obtained by clinic personnel, the study staff will obtain the information from your devices from your medical record
- The information collected by your Joslin physician and your diabetes educator about your diabetes care, changes in medications vital signs collected
- Complete 9 surveys/questionnaires to assess your diabetes awareness, quality of life, quality of your sleep, and your expectations. Each survey may take anywhere from 5 up to 15 minutes to complete, which can add up to 1 ½ - 2 hours to your clinic visit

Visit 1 – Week 0

Before any study procedures can be performed, you will be asked to read and sign this consent form.

This visit could last up to 1 ½ - 2 hours. This visit can be combined with a pump upgrade training session to be performed in the clinic.

Once all your questions have been addressed by a member of the study team:

- You will be asked to complete 9 surveys/questionnaires to assess your diabetes awareness, quality of life, and your expectations. Each survey may take anywhere from 5 up to 15 minutes to complete
- Immediately after this visit the study staff will: review and collect information from your medical record for the last year and for the duration of this study regarding your diabetes history and its treatment, vitals: height, weight, vital signs and diabetes technology use
- Download your pump, CGM and blood glucose meter data if it was not performed by clinic personnel. If the study staff downloads this information, it will be provided to you and your Joslin physician or diabetes educator for review as per clinical plan

Participant's Initials: _____

Visit 2 – Week 13 (± 2 weeks or per clinic plan)
Once all your questions have been addressed by a member of the study team:

- You will be asked to complete 9 surveys/questionnaires to assess your diabetes awareness, quality of life, and your expectations. Each survey may take anywhere from 5 up to 15 minutes to complete
- Immediately after this visit the study staff will: review and collect information from your medical record for the last year and for the duration of this study regarding your diabetes history and its treatment, vitals: height, weight, vital signs and diabetes technology use
- Download your pump, CGM and blood glucose meter data if it was not performed by clinic personnel. If the study staff downloads this information, it will be provided to you and your Joslin physician or diabetes educator for review as per clinical plan

Visit 3 – Week 52 (± 4 weeks or per clinic plan)
Once all your questions have been addressed by a member of the study team:

- You will be asked to complete 9 surveys/questionnaires to assess your diabetes awareness, quality of life, and your expectations. Each survey may take anywhere from 5 up to 15 minutes to complete
- Immediately after this visit the study staff will: review and collect information from your medical record for the last year and for the duration of this study regarding your diabetes history and its treatment, vitals: height, weight, vital signs and diabetes technology use
- Download your pump, CGM and blood glucose meter data if it was not performed by clinic personnel. If the study staff downloads this information, it will be provided to you and your Joslin physician or diabetes educator for review as per clinical plan

Risks, Potential Risks and/or Discomforts

Participating in research studies often involves some risks, possible risks and/or discomforts. It is possible that some of the questions in the questionnaire/surveys may make you uncomfortable, due to their personal nature about your diabetes care and quality of life.

In addition to the risks, possible risks and/or discomforts listed above, there may be risks/discomforts involved in this study that are not known at this time.

New Information and Questions

If you have any questions at any time about this study, you may contact the study investigator Dr. Osama Hamdy at (617) 309-2726 or the study coordinator Sahar Ashrafzadeh at (617) 309-4131.

Alternative Procedures/Treatments

You do not have to participate in this study to receive treatment for your condition. There are other treatments currently available. They include your current diabetes treatment.

Information for Women of Childbearing Potential

If you are a woman who is breast-feeding, pregnant, or wanting to become pregnant during the next 52 weeks, you may not participate in this study.

Participant's Initials: _____

If you have not been surgically sterilized, or have not undergone menopause at least one year ago, you must use something to prevent pregnancy, such as systemic hormones (birth control pills, implant), intrauterine device (IUD), or a barrier method (diaphragm with intravaginal spermicide, cervical cap, male or female condom).

If you suspect that you have become pregnant at any time or do not use one of the contraceptive methods recommended by the study investigator, you notify the study investigator or study staff. If you become pregnant, you will not be allowed to continue your participation in this research study.

Removal from Study

Your participation in this research study may be discontinued before you complete the study if circumstances arise which make this necessary. Your participation may be discontinued for any of the following reasons:

- Failure to complete the questionnaires/surveys
- Discontinuation from the 670G system
- Change in your medical condition
- Discontinuation of the study for any reason by the sponsor, investigator, Joslin Diabetes Center, or government agencies
- Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by research participants in this study

If you are discontinued from the study for any reason, this will have no affect on your current or future relationship with the Joslin Diabetes Center. You will not be penalized or lose any other benefits to which you are otherwise entitled.

Adverse Events or Injuries

If an adverse event or study related injury occurs as a direct result of taking part in this study, you should immediately contact the study investigator Dr. Osama Hamdy at (617) 309-2726 or the study coordinator Sahar Ashrafzadeh at (617) 309-4131.

In the event of an adverse event or study related injury, you or your insurance company may be responsible for some or all of your medical costs for any necessary medical treatment, which will be arranged by Dr. Osama Hamdy and the Joslin Diabetes Center.

It is not the policy of the Joslin Diabetes Center to provide free medical treatment or financial compensation for such things as lost wages, disability, and/or discomfort as a result of an adverse event or study related injury.

Anticipated Benefits

It is not expected that you will benefit directly from participating in this study. You should not expect your condition to improve as a result of participating in this research. This study is not being conducted to improve your condition or health.

While there is no guarantee that you will benefit by participating in this study, future research studies and subjects may benefit from this study.

Participant's Initials: _____

Remuneration/Reimbursement

You will be provided parking validation for Pilgrim road garage, for completing the study questionnaires/surveys during all study visits. You will also be provided a stipend of $10 for each study visit. You will receive a total of $30 if you complete all study visits.

Responsibility for Costs

You or your insurance company will not be billed for the costs of study related procedures and tests.

You or your insurance company may be responsible for the costs of insurance co-pays, and/or medications used during this study. These may include your insulin, pump supplies, CGM and home glucose meter and strips.

Right to Withhold or Withdraw Consent, or Refuse Procedures

Your consent to participate in this research study is completely voluntary. You do not have to give your consent, but you will not be allowed to participate in this research study without providing such consent.

At any time you may withdraw this consent and/or refuse a procedure.

If you withdraw your consent or refuse a procedure, you will not be allowed to continue your participation in this research study. To formally withdraw your consent to participate in this research study, you must provide a written and dated notice of this withdrawal to the study's investigator Dr. Osama Hamdy at the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

Whether or not you provide your consent to participate in this research study, withdraw your consent, or refuse a procedure will have no affect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with the Joslin Diabetes Center. You will not be penalized or lose any other benefits to which you are otherwise entitled.

Privacy & Confidentiality – HIPAA Authorization

A federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, you must provide written authorization for the use and/or disclosure of your medical information in connection with research involving your treatment or medical records.

This section gives more specific information about the privacy and confidentiality of your medical information. It explains what medical information will be collected during this research study and who may use, disclose or receive your medical information. It also describes how you can revoke this authorization after you sign this document and your right to inspect your medical information.

We will only collect medical information that is needed for this research study. Your medical information will only be used and/or disclosed as explained in this document or as permitted by law. The results of this research study may be published in scientific journals and/or presented at medical meetings. If the results of this study are published and/or presented, your identity will be kept confidential.

Participant's Initials: _____

In addition to this document, you will receive the Joslin Diabetes Center's Notice of Privacy Practices, which provides more information on how the Joslin Diabetes Center can use and/or disclose your medical information. If you have not received the Joslin Diabetes Center's Notice of Privacy Practices, please ask the study investigator or a member of the study staff.

Medical Information Involved in this Study

This study may involve the use and/or disclosure of medical information already in your medical record here at Joslin and/or in another health care provider's records. The information that will be used will be limited to information concerning:

- Diabetes history and treatment
- CGM, blood glucose meter and pump data

This medical information will be used and/or disclosed only for the purpose of this research study.

Additionally, this research study may generate new medical information that will be placed in your research record and kept at Joslin Diabetes Center. The nature of the medical information resulting from your participation in this research study that will be placed in your research record includes:

- Answers to study questionnaires and surveys

This medical information will be used and/or disclosed only for the purpose of this research study.

Access to Medical Information Involved in this Study

In addition to the study investigators listed on the first page of this document and their study staff, the following individuals may have access to your medical information involved in this study:

- Authorized representatives of the Joslin Diabetes Center Audit and Compliance Office;
- Authorized representatives of the Joslin Diabetes Center Committee on Human Studies;
- The sponsor of this study, or its agents, such as data repositories or contract research organizations;
- Governmental entities that have the right to see and/or review research and/or your medical information, such as the Office of Human Research Protections and the Food and Drug Administration;
- Hospital and other accrediting agencies;
- Clinical staff not involved in this study who may become involved in your care, if the medical information is potentially relevant to treatment;

All reasonable efforts will be used to protect the privacy and confidentiality of your medical information. However there is a risk of a breach of confidentiality that cannot be totally eliminated. To minimize this risk, study records will be kept in restricted areas at the Joslin Diabetes Center and computer access will be restricted by a password known only to the authorized members of the staff at the Joslin Diabetes Center. Information that could identify you, such as your name, will be maintained in a file separated from all study information. In spite of these efforts to protect the privacy and confidentiality of information about you, there is a risk that sensitive information may be obtained by others or discovered or inferred by members of your family. For example, a court of law may order Joslin to release confidential information about you.

Additionally, all reasonable efforts will be used to protect the privacy and confidentiality of your medical information when the Joslin Diabetes Center is authorized to disclose such information to others. However, if your medical information is disclosed to a party not required by law to keep it confidential, then that information may no longer be protected, and may subsequently be used and/or disclosed without your permission.

Participant's Initials: _____

Right to Withhold or Withdraw Authorization

Your authorization to use and/or disclose your medical information for the purpose of this research study is completely voluntary. You do not have to give your authorization, but you will not be allowed to participate in this research study without providing such authorization. At any time you may withdraw this authorization, but you will not be allowed to continue your participation in this research study.

If you withdraw your authorization, no new medical information about you will be obtained. However, medical information obtained for, or resulting from, your participation in this research study prior to the date you formally withdrew your authorization may continue to be used and/or disclosed for the purpose of this research study.

To formally withdraw your authorization to use and/or disclose your medical information for the purpose of this research study, you must provide a written and dated notice of this withdrawal to the study's Principal Investigators, Dr. Osama Hamdy at the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

Whether or not you provide or withdraw your authorization for the use and/or disclosure of your medical information for the purpose of this research study will have no effect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with the Joslin Diabetes Center. Additionally, whether or not you provide or withdraw your authorization will have no affect on your current or future relationship with a healthcare insurance provider.

Continuation of Authorization

Your authorization to use and/or disclose your medical information will continue until you withdraw your authorization. Your medical information may continue to be used and/or disclosed for this research study for an indefinite period of time. This is because information and data that is collected for this study will continue to be analyzed for many years and it is not possible to determine when such analysis will be complete.

Access to Medical Information

Except for certain legal limitations, you are permitted access to any medical information obtained for, or resulting from, your participation in this research study. However, you may access this information only after the study is completed.

Participant's Initials: _____

Joslin Diabetes Center, Informed Consent & Authorization (January 2007)

VOLUNTARY CONSENT & AUTHORIZATION

I understand that no one has contacted my primary care physician or any other doctor from whom I may be receiving care regarding my involvement in this research study. I understand that I should consult with any such doctor, and have been encouraged to do such, prior to participating in this study to discuss whether there is any reason he/she is aware of why I should not participate in this study.

I have been informed of and understand the purpose of the research study entitled "Evaluation of use and patient satisfaction of hybrid closed-loop Medtronic 670G in real-world clinical settings: Prospective Multistage Surveys" and the study's procedures. I have been informed of and understand the foreseeable risks, potential risks, discomforts, and benefits associated with this study. I have been advised of and understand that unforeseen complications may occur. I understand that I may or may not be entitled to free medical care or compensation in the event that I am injured as a result of my participation in this study. I understand that if this research study should result in the development of any marketable product, it is not expected that any profits would be shared with me.

I have been informed of and understand that my medical information may be used and/or disclosed for the purpose of this research study. I understand that the study investigators, study staff, and the Joslin Diabetes Center will make all reasonable efforts to protect my privacy and confidentiality. I have been advised of and understand that there is a risk that my medical information may be obtained by others. I have been advised of and understand that if others obtain my medical information, my medical information may no longer be protected, and may be subsequently used and/or disclosed without my permission. I have been informed of and understand that this study may be published or otherwise shared for scientific purposes. I understand that my name will not be published and that every reasonable effort will be made to protect my confidentiality.

I have been informed of and understand that my participation in this study is completely voluntary. I may refuse to consent to my participation in this study. Once enrolled in this study, I may withdraw my consent or refuse a procedure at any time. I may refuse to authorize the use and/or disclosure of my medical information for the purpose of this study. Once enrolled in this study, I may withdraw my authorization at any time. I have been informed of and understand that I will not be allowed to participate in this study, or continue my participation in this study, without both my consent and authorization.

I have read this document and been provided with the opportunity to discuss any questions and/or concerns regarding the research study and/or this document with the study investigator or a member of the study staff. I have received the Joslin Diabetes Center's Notice of Privacy Practices.

I have been informed of and understand that I may contact the Joslin Diabetes Center's Committee on Human Studies if I have questions regarding my rights as a research participant in this study. I may contact either:

- **Leigh A. Read**, CHS Program Administrator, at **(617) 309-2543**
- **Robert C. Stanton, M.D.**, CHS Chairperson, at **(617) 309-2477**

I have been informed of and understand that I may contact the Joslin Diabetes Center's Chief Audit and Compliance Office if I have questions regarding my rights associated with the use and/or disclosure of my medical information. I may contact:

- Joslin Diabetes Center's Compliance Officer, at **(617) 309-2400**

Participant's Initials: _____

This is a legal document that may affect my legal rights, my rights to privacy and my medical conditions and information. I understand that I have had the opportunity to consult with legal counsel, and my own physician about this study before signing this form.

I, _____ hereby consent to participate in this study and authorize the use and/or disclosure of my medical information for this research study, as described in this document.

_____ _____

Signature of Participant or Participant's Representative *Date*

_____ _____

Participant or Participant's Representative (Print Name) *Relationship to Participant*

PLEASE NOTE

I do not have to provide my authorization for the use and/or disclosure of my medical information for this research study, as described in this document. If I do not want to provide my authorization, I must check the box below and initial this statement. If I do not provide my authorization, I may not be able to participate in this study.

☐ I **do not** authorize the use and/or disclosure of my medical information for this research study, as described in this document. _____ Participant's Initials

Participant's Initials: _____

Joslin Diabetes Center, Informed Consent & Authorization (January 2007)

VERIFICATION OF EXPLANATION

I hereby certify that I have explained to the above-named participant the purpose of the study entitled "Evaluation of use and patient satisfaction of hybrid closed-loop Medtronic 670G in real-world clinical settings: Prospective Multistage Surveys", the nature of the study procedures, and such foreseeable risks, potential risks, discomforts, and benefits that may result from their participation in this study. This explanation was made in appropriate language. I have advised the above-named participant to contact their primary care doctor regarding his/her participation in this study, if such contact has not been previously made. I have asked the above-named participant if they have any questions and/or concerns regarding this research study or any of the study's procedures, and I have answered his/her questions to the best of my ability.

I hereby certify that I have explained to the above-named participant the nature and purpose of the use and/or disclosure of his/her medical information, including the possibility that his/her medical information may be obtained by others. This explanation was made in appropriate language. I have asked the above-named participant if they have any questions and/or concerns regarding the use and/or disclosure of his/her medical information for the purpose of this research study, and I have answered his/her questions to the best of my ability.

I hereby certify that I have informed the above-named participant that his/her participation in this research study is completely voluntary. To the best of my knowledge, the decisions made by the above-named participant regarding his/her consent and authorization are accurate reflections of his/her personal choices. To the best of my knowledge, the above-named participant has not been coerced or induced into his/her participation in this research study.

_____ _____

Signature of Investigator or Investigator's Representative *Date*

_____

Investigator or Investigator's Representative (Print Name)

Participant's Initials: _____