Joslin Diabetes Center

Committee on Human Studies

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Initial Approval Notification

November 22, 2017

Osama Hamdy, M.D., Ph.D.
Joslin Diabetes Center
One Joslin Place
Boston, MA 02215

Dear Dr. Hamdy:

This letter is to notify you of the Joslin Diabetes Center's Committee on Human Studies (CHS) approval of the following human subject research study.

Study Title	Evaluation of Use and Patient Satisfaction of Hybrid Closed-Loop Medtronic 670G in real-world Clinical Settings: Prospective Multistage Surveys
CHS Study Number	2017-14
Study Funding/Sponsor	Joslin Diabetes Center/Hamdy Research Funds

CHS Approval Date	August 18, 2017	***Approval Expiration Date***	August 17, 2018

Approved Study Documents

CHS Protocol/Protocol Application (dated 10/31/2017)
CHS Consent Form (dated 11/22/2017)
Study Questionnaires:

- PAID
- WHO-5 Well Being Index
- Health Service Utilization
- Diabetes Distress Scale (DDS)
- Hypoglycemic Fear Survey, Worry Subscale (HFS-W)
- Clarke Hypoglycemia Awareness Survey
- Sleep Quality Assessment (PSQI)
- SF Health Survey

CHS approval does not constitute final Joslin Diabetes Center authorization to conduct the study. You need to verify that all <u>non-IRB</u> administrative and financial issues have been addressed through the Office of Sponsored Research before individuals are recruited and enrolled in the study.

<u>Important Information for Investigators & Study Team Members</u>

- You must only use CHS approved copies of the consent form(s), study questionnaire(s), letter(s), advertisement(s), etc… for this study.
- Any modifications or change made to the study must be submitted to the CHS in writing for review. The CHS must approve all changes before they can be initiated.
- Any unanticipated problem involving risks to subjects or others or other reportable events *(i.e. serious and/or unexpected adverse event, death of a research subject, protocol deviation)* must be reported to the Committee according to CHS Policy, CHS-150, Reporting of Unanticipated Problems involving Risks to Research Subjects and Other Reportable Events.

- The expiration date of CHS approval for this study is stated above. Continuing review of the study is required prior to this date. It is your responsibility to complete the necessary requirements to secure continuing review approval prior to this date.

Clinical Trial Registration

Clinical Trial Registration may be required for this study per Food and Drug Administration and/or The International Committee of Medical Journal Editors (ICMJE) requirements. Please refer to the CHS guidance on the Joslin intranet on ClinicalTrials.gov registration or go to www.ClinicalTrials.gov.

If you have any questions about this information do not hesitate to contact the CHS at

Thank you.

Leigh A. Read, CIP, Manager, Research Compliance/Assurance & Programs
for the Committee on Human Studies

cc: CHS #2017-14 file

Joslin Diabetes Center

Committee on Human Studies

Application for Review and Approval of Research and Training Projects Involving Human Research

Principal Investigator(s): Osama Hamdy, MD, PhD

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

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

Funding: Internal funding, cost center: 001.14.395.01

Study Contact: Sahar Ashrafzadeh (617) 309-4131
Taha Elseaidy (617) 309-4145

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1. PURPOSE OF PROTOCOL:

As patients with type 1 diabetes are adopting diabetes technology i.e. insulin pumps and continuous glucose monitors (CGM) to manage their diabetes, little is known about how and which patients will derive the most benefit from these technologies (Ritholz 2008). Joslin clinic is about to use one of the most advanced technologies in this field called MiniMed 670G with SmartGuard™ Technology and Guardian® Sensor-3. This new system is commercially called hybrid closed-loop. It has been promoted as an advanced pump that can automatically adjust insulin delivery based on the interstitial glucose values captured continuously by the Guardian 3 sensor. The MiniMed 670G system adjust continuous

delivery of basal insulin (Insulin is delivered in microboluses every 5 minutes based on sensor glucose level) while administration of insulin boluses before meals and for correction has to be manually entered by the user as well announcement of exercise. The pump (MiniMed 2017) uses predictive algorithms to keep blood glucose levels within target range (blood glucose target is 120 mg/dl) with the goal to reduce severe hypo- or hyperglycemia. We postulate that this new technology may improve patients' quality of life and improve patients' satisfaction with diabetes management.

This investigator-initiated project will examine the use of the hybrid closed-loop Medtronic 670G in clinical settings through surveys conducted at different intervals of this technology use.

The project has two inter-related goals:

1) Evaluation of use of this new technology in clinic settings

2) Evaluation of patient's satisfaction and quality of life in response to this technology

2. *STUDY DESIGN/RECRUITMENT:*

This single center prospective study will involve prospective follow up of adult patients with type 1 diabetes who receive their care at the Joslin Diabetes Center in Boston. Only patients who will be started on Medtronic 670G will be eligible for this study. One hundred eligible patients will be enrolled in the study after receiving their proper training on using Medtronic 670G hybrid closed-loop system through the clinic pump program. Any intervention in relation to this pump or its technology will be conducted outside this study by the treating physician and certified diabetes educator. This study involves 3 visits to Joslin Diabetes Center of 52 weeks.
Prior to pump training session, potential participants will be contacted by the study coordinator to see if they would like to participate in this research study. Once the patients agree to learn more about the study, the coordinator will arrange with the patients to meet before or after their clinic pump upgrade session, as per clinical plan. At this session, eligibility will be confirmed by reviewing the inclusion and exclusion criteria and informed consent will be obtained.

Visit 1 – Week 0

Once informed consent has been obtained:

- Basic information demographic and clinical data will be captured from electronic health records: Height, weight, and blood pressure. Pertinent medical history including insulin dosages, diabetes history, and diabetes technology use history on file will be reviewed
- A copy of download glucose meter and insulin pump (if patient uses one) will be made
- If patient does not use insulin pump, records of most recent insulin regimen will be collected from medical record
- Most recent A1C will be recorded with its date
- Participants will be asked to fill the following surveys which would approximately take 1.5 - 2 hrs:
    - Problem Areas in Diabetes Questionnaire (PAID)
    - WHO-5 Well- Being Index
    - Health Service Utilization
    - Diabetes Distress Scale (DSS)
    - Hypoglycemia Fear Survey, Worry Scale (HFS_W)

- Technology Expectations Questionnaire
- Clarke Hypoglycemia Scale
- Sleep Quality Assessment Inventory (PSQI)
- SF36 Health Survey

Visit 2 – Week 13 (± 2 weeks) or per clinic plan

During this visit the following information will be collected:

- A copy of pump download and a copy of CGM download. The original downloaded pump/CGM data will be provided to the participant's Joslin provider for diabetes management
- After patient clinic visit, we will capture any new clinical information, vital signs, A1C and any medication adjustment from electronic health records
- A device check will be conducted to capture any problems with the timely refill of the sensor
- Participants will be asked to fill the following surveys which would approximately take 1.5 - 2 hrs:
  - Problem Areas in Diabetes Questionnaire (PAID)
  - WHO-5 Well- Being Index
  - Health Service Utilization
  - Diabetes Distress Scale (DSS)
  - Hypoglycemia Fear Survey, Worry Scale (HFS_W)
  - Technology Expectations Questionnaire
  - Clarke Hypoglycemia Scale
  - Sleep Quality Assessment Inventory (PSQI)
  - SF36 Health Survey

Visit 3 – Week 52 (± 4 weeks) or per clinic plan (final visit)

During this visit the following information will be collected:

- A copy of pump download and a copy of CGM download. The original downloaded pump/CGM data will be provided to the participant's Joslin provider for diabetes management
- After patient clinic visit, we will capture any new clinical information, vital signs, A1C and any medication adjustment from electronic health records
- A device check will be conducted to capture any problems with the timely refill of the sensor
- Participants will be asked to fill the following surveys which would approximately take 1.5 - 2 hrs:
  - Problem Areas in Diabetes Questionnaire (PAID)
  - WHO-5 Well- Being Index
  - Health Service Utilization
  - Diabetes Distress Scale (DSS)
  - Hypoglycemia Fear Survey, Worry Scale (HFS_W)
  - Technology Expectations Questionnaire
  - Clarke Hypoglycemia Scale
  - Sleep Quality Assessment Inventory (PSQI)
  - SF36 Health Survey

The questionnaires that will be administered are:

Problem Areas in Diabetes Questionnaire (PAID)- A validated tool that helps identify diabetes-related emotional distress. Administration time is approximately 5 minutes.

WHO-5 Well-Being Index- This is a validated, 5-question scale, utilized to assess general outlook and overall well-being. This scale also examines aspects other than just the absence of depressive symptoms. Administration time is approximately 5 minutes.

Health Service Utilization Form- This form captures the frequency of Emergency Room visits, calls to 911, after-hours/urgent care visits, hospital visits, the number of visits to their health care provider/physician/nurse practitioner office visits, as well as visits to dieticians. This form captures these visits whether diabetes-related or not. Additionally, this form captures self-care time and work/work capability status in relation to their diabetes needs. Time to completion is approximately 10 minutes.

Diabetes Distress Scale (DDS) - This scale lists 17 potential problem areas that people with diabetes may experience, and can denote the degree to which they are or are not affected. Administration time is approximately 10 minutes.

Hypoglycemic Fear Survey, Worry subscales (HFS-W) - This validated survey consists of 18 questions which measure several dimensions of anxiety and fear surrounding hypoglycemia among adults with diabetes. Administration time is approximately 10 minutes.

Clarke Hypoglycemia Scale– A validated tool that uses eight questions to assess awareness of hypoglycemia in adults. A score of 1 or 2 is classified as aware; a score of 3 or more is classified as impaired awareness of hypoglycemia (IAH). Administration time is approximately 10 minutes.

Sleep Quality Assessment Inventory (PSQI) - A validated tool used to screen patients for the presence of significant sleep disturbances. This will be used to assess whether patients are experiencing sleep disturbances with new diabetes technology (alarms). A total score of "5" or greater is indicative of poor sleep quality. Administration time is approximately 10 minutes.

SF36 Health Survey- the SF-36 Health Survey was developed at RAND as part of the Medical Outcomes Study. This survey taps eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health. Administration time is approximately 10-15 minutes.

3. INCLUSION / EXCLUSION CRITERIA

Inclusion Criteria

Individuals starting on Medtronic 670G hybrid closed-loop technology:

- Male and female patients with age >18 years old at the time of signing informed consent
- Type 1 diabetes ≥1 year prior to the day of screening
- Planning on upgrading to MiniMed 670G pump and sensor technology as per medical plan
- Treated and followed by an endocrinologist at Joslin Diabetes Center in Boston, MA

Exclusion Criteria.

- Pregnancy (self-reported) or planning conception in next 12 months
- Currently participating in another study that would affect the results of this study

4. DATA ANALYSIS

The study will evaluate both quantitative and qualitative parameters at the 3 collection points (0, 13 and 52 weeks). Both parametric and non-parametric statistical analyses will be used to analyze data.

The primary endpoints to be evaluated will be:

- Change in quality of life and patients satisfaction with this new technology
- Change in HbA1c from baseline
- Discontinuation from the MiniMed 670G system

Pre-specified secondary outcomes:
Proportions of participants with HbA1c <7.0%, <7.5%, relative reduction >10%, reduction >1.0%, and reduction >1% or HbA1c <7%

1- Time spent in closed-loop, and time spent in open-loop
2- Amount of time per day the glucose concentration was hypoglycemic <70, <60, and <50 mg/dL, hyperglycemic >180, >250, and >300 mg/dL, and in the target range of 70 to 180 mg/dL
3- Glucose variability assessed by computing the coefficient of variation
4- Changes in:
    a. Problem Areas in Diabetes Questionnaire (PAID)
    b. WHO-5 Well- Being Index
    c. Health Service Utilization
    d. Diabetes Distress Scale (DSS)
    e. Hypoglycemia Fear Survey, Worry Scale (HFS_W)
    f. Technology Expectations Questionnaire
    g. Clarke Hypoglycemia Scale
    h. Sleep Quality Assessment Inventory (PSQI)
    i. SF36 Health Survey

5. POSSIBLE BENEFITS:

Participants may benefit from use of the 670G hybrid closed-loop in a supervised manner. Data derived from this study may inform the development of new therapeutic strategies for management of diabetes that could benefit other individuals with diabetes.

6. POSSIBLE RISKS:

The risks to subjects for this study are overall quite minimal since all the study procedure is filling surveys and collecting clinical information.

Psychosocial Questionnaires

As part of the study, participants will complete psychosocial questionnaires which include questions about their private attitudes, feelings and behavior related to diabetes. It is possible that some people may find these questionnaires to be mildly upsetting. Similar questionnaires have been used in previous research and these types of reactions have been uncommon.

7. RECRUITMENT / SOURCE OF SUBJECTS:

Potential study subjects will be identified and approached for study participation from adult patients with type 1 diabetes who are upgrading to the new MiniMed 670 G system and who receive their care at the Joslin Diabetes Center in Boston, MA.

8. RIGHTS AND PRIVACY:

For security purposes, participants will be assigned an identifier that will be used instead of their name. Protected health information including device data gathered for this study will only be available to study staff. During each visit, the study devices will be downloaded to a clinic computer that is secured and password protected.

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Please answer the following questions:

- Will medical history/clinical information be obtained from the subjects' medical records for the purpose of this study? If yes, please list what information will be recorded.
  ☒ YES ☐ NO

  One year prior to study participation as well as during the duration of the study:
  - DM History
  - Vitals
  - A1c data
  - Diabetes technology use history
  - Current medications
  - Insulin doses, blood glucose and CGM data

- Will information resulting from this study (i.e. results of clinical/research lab tests, etc....) become part of the subjects' medical record or provided to the subject and/or others for clinical purposes? If, no, please list what information will not be given to the subject or recorded in their medical record and why.

  ☐ YES ☒ NO

Since this is an observational study most data will already be in the study participant's medical record. The data from questionnaires will be made available to the participant upon request but it will not be part of the medical record.

- Will subjects' identifiable health information* be shared with others outside of Joslin Diabetes Center? If yes, list whom this information will be shared with (please be specific, include names of collaborators, study sponsor contacts)?

  ☐ YES ☒ NO

9. OMIT PROCEDURES / LEAVE STUDY:

Patients will be free at any time to leave the study without bias to their clinical care or any information about their own study results.

10.INCENTIVES / REMUNERATION:

Study participants will receive parking validation at the Pilgrim Rd. garage for study visits 1, 2 and 3 when questionnaires are completed. In addition, participants will receive a $10 stipend for completing the surveys at each visit. Subjects could receive up to $ 30.00 if they complete all study visits.

*** Identifiable Health Information**

Data that includes any of the following identifiers are considered identifiable health information:

- Name
- Social Security number
- Medical Record Number
- Address by Street Location
- Address by Town/City/Zip Code
- Date of Birth
- Admission or Discharge Date
- Date of Death
- Telephone Number
- Fax Number
- Electronic E-Mail Address
- Web URLs
- Internet Protocol (IP) Address
- Health Plan Beneficiary Number
- Account Number
- Certificate/License Number
- Vehicle Identification Number and Serial Number, including License Plate Number
- Medical Device Identifiers and Serial Numbers
- Biometric Identifiers (finger and voice prints)
- Full Face Photographic Image
- Any Other Identifier likely to identify the subject

Please answer the following questions:

11. Where and how will your project utilize the Joslin Diabetes Center?

- ☐ General Clinical Research Center (GCRC)
- ☐ Clinical Trials Unit (CTU)
- ☒ Joslin Clinic
- ☐ Eye Unit
- ☐ Other (please specify) _____

12. Will your project involve research on living human fetuses?

- ☐ Yes
- ☐ No

13. Does your project involve the use of any new drug or device?

- ☐ Yes IND# or IDE# _____
- ☒ No

14. Is review required by risk management foundation?

- ☐ Yes
- ☒ No

_____ _____

Signature of Principal Investigator ***Date***

I have read and reviewed this application for approval by the Committee on Human Studies

_____ _____

Signature of PI's Section Head ***Date***

Please bring the original and twenty-four (24) copies of
this form and the informed consent form for the above research project to
Leigh Read in the Office of Sponsored Research
by the appropriate CHS meeting deadline.

References

- MiniMed, M. (2017). "Minimed (r) 670G System User Guide REF MMT-1780."
- Ritholz, M. (2008). "Is Continuous Glucose Monitoring for Everyone? Consideration of Psychosocial Factors." Diabetes Spectrum **21**(4): 287-289.

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.

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: _____

ID _____ PAID Date _____

INSTRUCTIONS: Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem ▼	Minor problem ▼	Moderate problem ▼	Somewhat serious problem ▼	Serious problem ▼
1. Not having clear and concrete goals for your diabetes care?	0	1	2	3	4
2. Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
3. Feeling scared when you think about living with diabetes?	0	1	2	3	4
4. Uncomfortable social situations related to your diabetes care (e.g., people telling you what to eat)?	0	1	2	3	4
5. Feelings of deprivation regarding food and meals?	0	1	2	3	4
6. Feeling depressed when you think about living with diabetes?	0	1	2	3	4
7. Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
8. Feeling overwhelmed by your diabetes?	0	1	2	3	4
9. Worrying about low blood sugar reactions?	0	1	2	3	4
10. Feeling angry when you think about living with diabetes?	0	1	2	3	4
11. Feeling constantly concerned about food and eating?	0	1	2	3	4
12. Worrying about the future and the possibility of serious Complications?	0	1	2	3	4
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4
14. Not "accepting" your diabetes?	0	1	2	3	4
15. Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
17. Feeling alone with your diabetes?	0	1	2	3	4
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	0	1	2	3	4
19. Coping with complications of diabetes?	0	1	2	3	4
20. Feeling "burned out" by the constant effort needed to manage diabetes?	0	1	2	3	4

Approved
Joslin CH

Partipant ID: _____ Date: _____

WHO-5 Well-Being Index

DIRECTIONS: Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.
Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

Over the last two weeks:	**All of the time**	**Most of the time**	**More than half of the time**	**Less than half of the time**	**Some of the time**	**At no time**
1. I have felt cheerful and in good spirits.	5	4	3	2	1	0
2. I have felt calm and relaxed.	5	4	3	2	1	0
3. I have felt active and vigorous.	5	4	3	2	1	0
4. I woke up feeling fresh and rested.	5	4	3	2	1	0
5. My daily life has been filled with things that interest me.	5	4	3	2	1	0

Partipant ID: _____ Date: _____

Health Service Utilization

☐ **Not Done** *If not done, reason* _____
If Done, please complete the following

1. In the last 6 months, have you gone to the Emergency Room without an ambulance?

☐ Yes ☐ No ☐ Don't know

If yes, complete the following:

1a. How many times did you go to the Emergency Room without an ambulance? _____ [1-9; >9]

1b. Number of times you went to the Emergency Room without an ambulance for:

1b1. Hypoglycemia (low blood sugars) _____ [0-9; >9]

1b2. Hyperglycemia (high blood sugars) _____ [0-9; >9]

1b3. Other reasons related to diabetes _____ [0-9; >9]

1b4. Reasons unrelated to diabetes _____ [0-9; >9]

2. In the last 6 months, has 911 been called because of your medical condition?

☐ Yes ☐ No ☐ Don't know

If yes, complete the following:

2a. How many times was 911 called (either by yourself or someone acting on your behalf)? _____ [1-9; >9]

2b. Number of times 911 was called for:

2b1. Hypoglycemia (low blood sugars) _____ [0-9; >9]

2b2. Hyperglycemia (high blood sugars) _____ [0-9; >9]

2b3. Other reasons related to diabetes _____ [0-9; >9]

2b4. Reasons unrelated to diabetes _____ [0-9; >9]

2c. How many times did the call to 911 result in the emergency medical service (ambulance) coming for your care? _____ [0-9; >9,

2c1. How many times did the ambulance take you to the emergency room? _____ [0-9; >9]

3. In the last 6 months, have you had to use an After Hours or Urgent Care Medical Clinic (other than an Emergency Room)?

☐ Yes ☐ No ☐ Don't know

If yes, complete the following:

3a. How many times did you go to the After Hours or Urgent Care Medical Clinic? _____ [1-9; >9]

3b. How many times did you go to the After Hours or Urgent Care Medical Clinic for:

3b1. Hypoglycemia (low blood sugars) _____ [0-9; >9]

3b2. Hyperglycemia (high blood sugars) _____ [0-9; >9]

3b3. Other reasons related to diabetes _____ [0-9; >9]

3b4. Reasons unrelated to diabetes _____ [0-9; >9]

4. In the last 6 months, have you had to be admitted to the Hospital?

☐ Yes ☐ No ☐ Don't know

If yes complete the following:

4a. How many times were you admitted to the Hospital?
_____ [1-9; >9]

4b. How many times were you admitted to the Hospital for:

4b1. Hypoglycemia (low blood sugars) _____ [0-9; >9]

4b1i. # of days for all hypoglycemia admissions:_____ [Range: 0-183]

4b2. Hyperglycemia (high blood sugars) _____ [0-9; >9]

4b2i. # of days for all hyperglycemia admissions:_____ [Range: 0-183]

4b3. Other reasons related to diabetes _____ [0-9; >9]

4b3i. # of days for all diabetes related admissions:_____ [Range: 0-183]

4b4. Other reasons unrelated to diabetes _____ [0-9; >9]

4b4i. # of days for all non-diabetes related admissions:_____ [Range: 0-183]

5. In the last 6 months, have you seen a health care provider like a physician or nurse practitioner for an office visit? ***(not including scheduled study visits)***

☐ Yes ☐ No ☐ Don't know

If yes complete the following:

5a. How many *times* have you seen a health care provider like a physician or nurse practitioner for an office visit for only reasons related to diabetes? _____ [0-9; >9] ☐ Unknown

5b. How many *times* have you seen a health care provider like a physician or nurse practitioner for an office visit for only reasons unrelated to diabetes? _____ [0-9; >9] ☐ Unknown

5c. How many *times* have you seen a health care provider like a physician or nurse practitioner for an office visit for both (reasons related and unrelated to diabetes)? _____ [0-9; >9] ☐ Unknown

5d. How many times during the office visits did you have a hemoglobin A1C test (to measure the control of your diabetes)? _ [0-9; >9] ☐ Unknown

6. In the last 6 months, have you seen a dietician?

☐ Yes ☐ No ☐ Don't know

If Yes, complete the following:

6a. How many times have you seen a dietician? _____ [0-9; >9] ☐ Unknown

Approved by Joslin CHS

7. **How many hours per day do you currently devote to managing your glucose levels (ie. looking at sugar levels, modifying your meals and/or your insulin dose)?** _____ Hours ☐ Unknown

8. **Are you currently or have been in the last 6 months doing any work for pay (part-time or full-time)?**

☐ Yes
☐ No
☐ I am retired
☐ I am not employed
☐ I would not like to disclose

If yes complete the following:

8a. How many days of work have you missed in the past 6 months because of your diabetes?
_____ Days ☐ Unknown

8b. How many days at work in the past 6 months have you been at work but unable to perform at half or more of your ability because of your diabetes? _____ Days ☐ Unknown

Partipant ID: _____ Date: _____

Diabetes Distress Scale (DDS)

DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
2. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
3. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
7. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
8. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10. Feeling that diabetes controls my life.	1	2	3	4	5	6
11. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

Partipant ID: _____ Date: _____

Hypoglycemic Fear Survey, Worry subscale (HFS-W)

DIRECTIONS: Below is a list of concerns people with diabetes sometimes have about low blood sugar. Please read each item carefully (do not skip any). Circle one of the numbers to the right that best describes how often in the last 6 months you WORRIED about each item because of low blood sugar.

Because my blood sugar could go low, I worried about...	Never	Rarely	Sometimes	Often	Almost always
1. Not recognizing/realizing I was having low blood sugar.	0	1	2	3	4
2.Not having food, fruit, or juice available.	0	1	2	3	4
3. Passing out in public.	0	1	2	3	4
4. Embarrassing myself or my friends in a social situation.	0	1	2	3	4
5. Having a hypoglycemic episode while alone.	0	1	2	3	4
6. Appearing stupid or drunk.	0	1	2	3	4
7. Losing control.	0	1	2	3	4
8. No one being around to help me during a hypoglycemic episode.	0	1	2	3	4
9. Having a hypoglycemic episode while driving.	0	1	2	3	4
10. Making a mistake or having an accident.	0	1	2	3	4

Because my blood sugar could go low, I worried about...	Never	Rarely	Sometimes	Often	Almost always
11. Getting a bad evaluation or being criticized.	0	1	2	3	4
12. Difficulty thinking clearly when responsible for others.	0	1	2	3	4
13. Feeling lightheaded or dizzy.	0	1	2	3	4
14. Accidently injuring myself or others.	0	1	2	3	4
15. Permanent injury or damage to my health or body.	0	1	2	3	4
16. Low blood sugar interfering with important things I was doing.	0	1	2	3	4
17. Becoming hypoglycemic during sleep.	0	1	2	3	4
18. Getting emotionally upset and difficult to deal with.	0	1	2	3	4

Partipant ID: _____ Date: _____

Clarke Hypoglycemia Awareness Survey

	☐ **Participant did not complete a Hypoglycemia Unawareness Survey** *If Participant did not complete a Hypoglycemia Unawareness Survey, please provide details in the COMMENTS section*

SURVEY COMPLETION DATE	
	1. **Date survey completed:** __/__/____

HYPOGLYCEMIA UNAWARENESS SURVEY	
	1. Select the category that best describes you: ○ I always have symptoms when my blood sugar is low ○ I sometimes have symptoms when my blood sugar is low ○ I no longer have symptoms when my blood sugar is low
	2. Have you lost some of the symptoms that used to occur when your blood sugar was low? ○ Yes ○ No
	3. In the past six months how often have you had moderate hypoglycemia episodes? *(Episodes where you might feel confused, disoriented, or lethargic and were unable to treat yourself)* ○ Never ○ Once or twice ○ Every other month ○ Once a month ○ More than once a month

Approved by Joslin CHS

	4. In the past year how often have you had severe hypoglycemic episodes? *(Episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose)* o Never o 1 time o 2 times o 3 times o 4 times o 5 times o 6 times o 7 times o 8 times o 9 times o 10 times o 11 times o 12 or more times
	5. How often in the last month have you had readings <70 mg/dL with symptoms? o Never o 1 to 3 times o 1 time/week o 2 to 3 times/week o 4 to 5 times/week o Almost daily

	6. How often in the last month have you had readings <70 mg/dL without any symptoms? ○ Never ○ 1 to 3 times ○ 1 time/week ○ 2 to 3 times/week ○ 4 to 5 times/week ○ Almost daily
	7. How low does your blood sugar need to go before you feel symptoms? ○ 60-69 mg/dL ○ 50-59 mg/dL ○ 40-49 mg/dL ○ <40 mg/dL
	8. To what extent can you tell by your symptoms that your blood sugar is low? ○ Never ○ Rarely ○ Sometimes ○ Often ○ Always

COMMENTS

Approved b
Joslin CHS

Name_____ Date_____

Sleep Quality Assessment (PSQI)

What is PSQI, and what is it measuring?

The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in adults. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

During the past month,

1. When have you usually gone to bed? _____
2. How long (in minutes) has it taken you to fall asleep each night? _____
3. What time have you usually gotten up in the morning? _____
4. A. How many hours of actual sleep did you get at night? _____
   B. How many hours were you in bed? _____

5. During the past month, how often have you had trouble sleeping because you	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
A. Cannot get to sleep within 30 minutes				
B. Wake up in the middle of the night or early morning				
C. Have to get up to use the bathroom				
D. Cannot breathe comfortably				
E. Cough or snore loudly				
F. Feel too cold				
G. Feel too hot				
H. Have bad dreams				
I. Have pain				
J. Other reason (s), please describe, including how often you have had trouble sleeping because of this reason (s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
9. During the past month, how would you rate your sleep quality overall?	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)

Scoring

Component 1	#9 Score	C1 _____
Component 2	#2 Score (<15min (0), 16-30min (1), 31-60 min (2), >60min (3)) + #5a Score (if sum is equal 0=0; 1-2=1; 3-4=2; 5-6=3)	C2 _____
Component 3	#4 Score (>7(0), 6-7 (1), 5-6 (2), <5 (3)	C3 _____
Component 4	(total # of hours asleep) / (total # of hours in bed) x 100 >85%=0, 75%-84%=!, 65%-74%=2, <65%=3	C4 _____
Component 5	# sum of scores 5b to 5j (0=0; 1-9=1; 10-18=2; 19-27=3)	C5 _____
Component 6	#6 Score	C6 _____
Component 7	#7 Score + #8 score (0=0; 1-2=1; 3-4=2; 5-6=3)	C7 _____

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Add the seven component scores together _____ *Global PSQI* _____

A total score of "5" or greater is indicative of poor sleep quality.
If you scored "5" or more it is suggested that you discuss your sleep habits with a healthcare provider

SF36 Health Survey

INSTRUCTIONS: This set of questions asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question please give the best answer you can.

1. In general, would you say your health is: (Please tick **one** box.)
   - Excellent ☐
   - Very Good ☐
   - Good ☐
   - Fair ☐
   - Poor ☐

2. Compared to one year ago, how would you rate your health in general now? (Please tick **one** box.)
   - Much better than one year ago ☐
   - Somewhat better now than one year ago ☐
   - About the same as one year ago ☐
   - Somewhat worse now than one year ago ☐
   - Much worse now than one year ago ☐

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? **(Please circle one number on each line.)**

	Activities	Yes, Limited A Lot	Yes, Limited A Little	Not Limited At All
3(a)	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
3(b)	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
3(c)	Lifting or carrying groceries	1	2	3
3(d)	Climbing **several** flights of stairs	1	2	3
3(e)	Climbing **one** flight of stairs	1	2	3
3(f)	Bending, kneeling, or stooping	1	2	3
3(g)	Waling **more than a mile**	1	2	3
3(h)	Walking **several blocks**	1	2	3
3(i)	Walking **one block**	1	2	3
3(j)	Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	(Please circle one number on each line.)	Yes	No
4(a)	Cut down on the **amount of time** you spent on work or other activities	1	2
4(b)	Accomplished less than you would like	1	2
4(c)	Were **limited** in the **kind** of work or other activities	1	2
4(d)	Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (e.g. feeling depressed or anxious)?

	(Please circle one number on each line.)	Yes	No
5(a)	Cut down on the **amount of time** you spent on work or other activities	1	2
5(b)	Accomplished less than you would like	1	2
5(c)	Didn't do work or other activities as **carefully** as usual	1	2

Approved b
Joslin CHS

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups? (Please tick **one** box.)

- Not at all ☐
- Slightly ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

7. How much physical pain have you had during the past 4 weeks? (Please tick **one** box.)

- None ☐
- Very mild ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Very Severe ☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Please tick **one** box.)

- Not at all ☐
- A little bit ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

9. These questions are about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that is closest to the way you have been feeling for each item.

	(Please circle one number on each line.)	**All of the Time**	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
9(a)	Did you feel full of life?	1	2	3	4	5	6
9(b)	Have you been a very nervous person?	1	2	3	4	5	6
9(c)	Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
9(d)	Have you felt calm and peaceful?	1	2	3	4	5	6
9(e)	Did you have a lot of energy?	1	2	3	4	5	6
9(f)	Have you felt downhearted and blue?	1	2	3	4	5	6
9(g)	Did you feel worn out?	1	2	3	4	5	6
9(h)	Have you been a happy person?	1	2	3	4	5	6
9(i)	Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.) (Please tick **one** box.)

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little of the time ☐
- None of the time ☐

11. How TRUE or FALSE is each of the following statements for you?

	(Please circle one number on each line.)	**Definitely True**	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
11(a)	I seem to get sick a little easier than other people	1	2	3	4	5
11(b)	I am as healthy as anybody I know	1	2	3	4	5
11(c)	I expect my health to get worse	1	2	3	4	5
11(d)	My health is excellent	1	2	3	4	5

Thank You!

Approved b
Joslin CHS