Version Date: 11/08/23

CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project:	Decreasing Stress in Diabetes: A Randomized Controlled Trial (DE-STRESS)
Principal Investigator:	Nazia Raja-Khan, M.D.
Address:	Penn State Health M.S. Hershey Medical Center Division of Endocrinology, Diabetes, and Metabolism 500 University Drive, H044 Hershey, PA 17033
Telephone Numbers:	Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-8395. After hours call (717) 531-8521. Ask for the Endocrinology doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?

We are asking you to take part in this voluntary research study because you have diabetes. Diabetes is a condition in which your blood glucose (also called blood sugar) levels are high. Over time high blood glucose levels can damage your eyes, kidneys, heart, blood vessels, and other organs.

What is the purpose of this research study?

The purpose of this research study is to find out how two different live online stress reduction programs affect blood glucose levels in people with diabetes.

How long will the research study last?

The research study lasts approximately six to eight and a half months.

What will I need to do?
After you sign this consent form, you will undergo a Screening Visit via video-conferencing (Penn State Health (PSH) Teams) or at the Clinical Research Center (CRC) at Hershey Medical Center. If you prefer, the entire study can be conveniently done from the comfort of your home using video-conferencing. Video-conferencing is a type of online meeting where two or more people engage in a live audio-visual call where they can see, hear, and talk to each other in real time, no matter where in the world they are. Due to the potential impact of COVID-19 on the opening of the CRC, it may be necessary for your study visits to be performed remotely via video-conferencing (PSH Teams). You will not have to fast for the Screening Visit. If the Screening Visit is via video-conferencing, you will be asked to obtain a small finger stick sample of blood using a Home A1CNow Self Check kit. If the Screening Visit is in the CRC, a single sample of blood will be drawn to determine if you are eligible for the study. During the Screening Visit, you will complete questionnaires. Because individuals are not eligible for our study if they have certain untreated mental health conditions, such as bipolar disorder, suicidality, or substance abuse, you will be interviewed by a member of the study team to see if you meet criteria for any of those conditions. After screening, if you are eligible to continue in the study, you will be asked to complete three more study visits via video-conferencing or at the CRC. We will ask you to complete a paper or electronic baseline medical history form at home.

At Study Visit #1/Baseline Study Visit, you will complete questionnaires. You will be asked to obtain a small finger stick sample of blood using a Home A1CNow Self Check kit. You will be asked to bring your smartphone, glucometer, continuous glucose monitor (CGM) and insulin pump (if applicable) to this remote or in-person visit. The study team will collect data from your glucometer, and also from your continuous glucose monitor and insulin pump if you use these devices. ***If you opt-in*** to wearing an Actigraph device, you will be provided with a wearable Actigraph device for monitoring your physical activity. You will be asked to wear the Actigraph for 7 days. In the 3 weeks around your baseline and subsequent study visits, ***if you opt-in*** to completing the food intake surveys, you will be asked to complete two ASA24 surveys about your food intake. Each ASA24 food intake survey will be sent to you as a link in an email, and will take approximately 30 minutes to complete. If the Baseline Visit is in the CRC, you will present to the CRC fasting meaning nothing to eat or drink (except for water) for at least 10 hours prior to your visit. You will undergo a brief physical exam. Blood samples will be drawn. Saliva samples will be collected. Hair (***optional***) and nail (***optional***) samples will be collected, if you give permission to providing these samples.

After the Baseline Visit, you will be randomly assigned to one of two groups for 6 months. The two groups are two different live online stress reduction programs, one of which is combined with health education. Once you are assigned to a stress reduction group, you will participate in the following 14 study sessions online in a live interactive virtual classroom using video-conferencing (Penn State University (PSU) Zoom):

- Orientation: This is one session that will last 1 and a half to 2 hours. You must attend Orientation to continue in the study.
- Class #1 to 8: These are eight sessions. These sessions will occur once a week for eight weeks after Orientation. Each of these sessions will last 2 and a half to 3 hours.
- Retreat: This is one session that will last 7 hours.
- Booster sessions #1 to 4: These are four sessions. These sessions will occur once a month in Months 3, 4, 5, and 6. Each Booster will last 45-minutes.

During these study sessions, you will be asked to participate in one or more of the following activities: breathing exercises, meditation, stretching exercises or health education activities. Study sessions will

consist of small groups of approximately 15 to 20 study participants. Each session will be led by an instructor. During the study, you will be asked to spend at least 25 to 30 minutes a day (for six days per week), outside of the sessions, doing home practice including reviewing the materials covered in the sessions, practicing activities related to your study sessions, or listening to excerpts of audio books. During the study, you will receive an email once a day asking you questions about your home practice.

After starting the study sessions, you will complete a follow-up phone call with the research coordinator after Class #4 (Study Visit #2), and two more study visits via video-conferencing or at the CRC at 2 months (Study Visit #3) and at 6 months (Study Visit #4/Final Visit). The baseline procedures described above will be repeated during the 2-month and 6-month study visits.

What are the main risks of taking part in the study?
For this study, the main risks to know about are:

- If you are on certain diabetes medications, such as insulin or a sulfonylurea, you may be at risk for low blood glucose (hypoglycemia) during or after the stress reduction sessions or home practice due to the effects of stress reduction or exercising on your blood glucose. You may also be at risk for low blood glucose while fasting for the study visits. Your medications may need to be adjusted. You are advised to ask your physician for instructions on adjusting your diabetes medications, if needed, while fasting, participating in the stress reduction sessions, or doing the home practice.
- The discomfort associated with removing blood by venipuncture (by needle from a vein) is a slight pinch or pin prick when the sterile needle enters the skin. The risks include mild discomfort and/or a black and blue mark at the site of puncture.
- There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.
- Stress reduction programs have been used in a variety of patient populations, including patients with serious medical illnesses. There is a risk of increased distress with stress reductions interventions due to increased awareness of stress. Potential risks include: increased depression, anxiety or panic, re-experiencing of traumatic memories [especially if there is a history of trauma or post-traumatic stress disorder (PTSD)], headaches, body pain, unable to sleep (insomnia), feeling disconnected from everything around you (dissociation) and unable to think clearly and/or make decisions (executive dysfunction).

What are the possible benefits to me that may reasonably be expected from being in the research?
There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include reduced stress, improved quality of life and overall well-being, education about nutrition and exercise, and possibly better blood glucose control.

What happens if I do not want to be in this research?
You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive commercially available treatments, including medications used to treat diabetes, as well as Diabetes Education, medical nutrition therapy, counseling, and other exercise or stress reduction program, after talking with your physician.
- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition, after talking with your physician.

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DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?

We are asking you to take part in this voluntary research study because you have diabetes. Diabetes is a condition in which your blood glucose (also called blood sugar) levels are high. Blood glucose is the main sugar found in the blood and the body's main source of energy. Blood glucose levels are high in people with diabetes because their bodies are not able to efficiently use the glucose in their blood for energy. Over time high blood glucose levels can damage your eyes, kidneys, heart, blood vessels, and other organs. For many people with diabetes, both medication and lifestyle management are needed to control blood glucose levels. Studies have shown that stress is common in people with diabetes, and related to worse blood glucose control and poorer health outcomes. This research is being done to find out how two different live online stress reduction programs affect blood glucose levels in people with diabetes.

Approximately 520 people will take part in this research study at Penn State Health.

2. What will happen in this research study?

If you prefer, the entire study can be conveniently done from the comfort of your home using video-conferencing (Zoom or Teams). Video-conferencing is a type of online meeting where two or more people engage in a live audio-visual call where they can see, hear, and talk to each other in real time, no matter where in the world they are.

You will complete study visits via video-conferencing or at the Clinical Research Center (CRC) at Hershey Medical Center. Due to the potential impact of COVID-19 on the opening of the CRC, it may be necessary for your study visits to be performed via video-conferencing. In addition to completing study visits, you will participate in a live online stress management course via video-conferencing. The research coordinator will provide you with the dates and times for all the live online sessions in the upcoming wave/semester. If you think you will miss Orientation, or if you think you will miss more than 2 classes during the first 8 weeks (including Class #1 to 8 and the Retreat), you will be encouraged to wait for another wave/semester when you are able to make the time commitment. You must attend Orientation. If you miss Orientation, you will not be able to continue in the study.

SCREENING VISIT and procedures

We will schedule a screening visit via video-conferencing (PSH Teams) or at the CRC to assess eligibility within 10 weeks before Orientation. After signing this consent form, you will complete questionnaires to further assess your eligibility. Your medical records may also need to be reviewed to confirm that you have diabetes and are eligible to continue in the study. You will be asked questions about your medical history. Because individuals are not eligible for our study if they have certain untreated mental health conditions, such as bipolar disorder, suicidality, or substance abuse, you will be interviewed by a member of the study team to see if you meet criteria for any of those conditions.

Participating in this research study will not deny any appropriate medical care or mental health care you would ordinarily receive from your primary care provider, mental health provider, or other health care providers. Names and doses of medications will be collected throughout the study.

You will not need to fast for the screening visit. If the screening visit is via video-conferencing, you may be asked to obtain a small finger stick sample of blood to measure your hemoglobin A1c using a Home A1CNow Self Check kit that will be mailed to you, or you may come to a Penn State Health clinical laboratory where they can obtain a single sample of approximately 2 tablespoons (30 mL) of blood to measure your hemoglobin A1c level, which is a measure of your average Blood glucose over the past 3 months. If the screening visit is in the CRC, a single sample of approximately 2 tablespoons (30 mL) of blood will be drawn to measure your hemoglobin A1c. If you already had a hemoglobin A1c checked within 12 weeks before the Orientation session, these records may be obtained and accepted in lieu of repeating the test for screening. If you are a woman of childbearing age (55 years old or younger), a urine pregnancy test may be checked and if you are pregnant, you will be excluded from participation in the study. If the screening visit is done remotely, you will be mailed a urine pregnancy test when applicable. It is possible that the results of these evaluations will show that you are not a candidate to proceed further with the study.

At the end of the screening visit, if you remain eligible to continue in the study, you will be scheduled for a baseline visit via video-conferencing or at the CRC, and the following additional procedures will be completed at the screening visit:

- The research coordinator will work with you to ensure that the dates and times on your diabetes devices (glucometers, CGM, insulin pump, and other smart insulin delivery devices) are correct, in preparation for the collection of data from these devices at your future study visits.
- You will be given instructions on how to complete the ***optional*** ASA24 food intake survey.
- You will be given a paper or electronic baseline medical history form, and asked to complete it at home.

BASELINE VISIT (VISIT #1)

The baseline visit will be scheduled via video-conferencing or at the CRC within 6 weeks before the Orientation. The baseline visit will last approximately 3 hours. You will be asked to provide the following for your remote or in-person baseline visit:

- The completed baseline medical history form you were given at the screening visit. You will complete this electronically or on paper. If you complete a paper form, you will be asked to mail it back. You can also bring the paper form to your baseline visit if it is being done in the CRC.
- A list of your current medications and supplements
- Your smartphone if you have one
- Your diabetes devices (glucometers, CGM, insulin pump & other smart insulin delivery devices)
- Home A1C Now Self Check kit if you received one at the screening visit

At the baseline visit, you will be asked to obtain a small finger stick sample of blood using a Home A1CNow Self Check kit that will be mailed to you. You will be asked to complete questionnaires about your medical history, mood, quality of life and overall health and well-being. There will also be a COVID-19 questionnaire administered, to obtain information about how your life has been affected by the pandemic. These questionnaires will be repeated at the 2-month and 6-month study visits. At your baseline visit only, you will be asked to complete a questionnaire regarding your childhood, including information on sensitive topics. You are free to skip any questions that you would prefer not to answer. Ensuring the safety of all trial participants is paramount.

- The research coordinator will collect data from diabetes devices you are using (glucometers, CGM, insulin pump, & other smart insulin delivery devices) at the remote or in-person baseline visit, as well as at subsequent visits. You may be asked to share data reports from your devices with the study team.
- The research coordinator may use computer software to collect the data from your devices.
- The research coordinator may ask to look through the data in your device and record it.
- If you are using a CGM, the research coordinator may use the secure cloud based diabetes-management system for your CGM (e.g. LibreView or Dexcom Clarity) to collect your CGM data anonymously using your study ID number instead of your name or other identifying information.

Throughout the study, if you are not using a CGM, you will be advised to use your own glucometer and testing supplies to check your blood glucose at least four times a day, including:

- Fasting (before breakfast or the first meal of the day)
- Before lunch
- Before dinner
- Before bed
- When having symptoms

This is in-line with general recommendations for patients with uncontrolled diabetes, or patients on multiple daily injections of insulin or an insulin pump. If you are testing fewer than 4 times a day, you are advised to alternate your testing times e.g. check fasting and before lunch on some days, fasting and before evening meal on other days, and fasting and before bed on other days.

If you are a woman of childbearing age (55 years old or younger), a urine pregnancy test may be checked and if you are pregnant, you will be excluded from participation in the study. If the baseline visit is done remotely, you will be mailed a urine pregnancy test when applicable.

After the baseline visit, you will start to receive an email survey once a day asking you to rate your stress level and food cravings.

BASELINE VISIT – OPTIONAL PROCEDURES

Upon entry into the study, you will be given instructions on how to complete the ***optional*** ASA24 food intake survey. ***If you opt-in*** to completing the food intake surveys, around your baseline visit you will be emailed a link to the ASA24 survey and asked to record your food intake for the previous day. You will complete two ASA24 surveys about your food intake. Each ASA24 food intake survey will take approximately 30 minutes to complete. This will be repeated around your 2-month and 6-month study visits. You may opt-out of completing the ASA24 food intake surveys at the end of this consent form, and will still be permitted to continue in the study.

If you opt-in to wearing an Actigraph device for monitoring your physical activity, the research coordinator will provide you with an Actigraph around the baseline visit. The Actigraph is a small device that comes with a belt that you will be asked to wear around your waist for 7 days. You will be asked to wear the Actigraph during all waking hours, removing it only for sleep or before showering or swimming. You will be asked to mail the Actigraph back to the study team, after the 7 day wear time, in a pre-stamped envelope, along with a wear time log/diary. This will be repeated around your 2-month and 6-month study visits. You may opt-out of wearing the Actigraph at the end of this consent form, and will still be permitted to continue in the study.

BASELINE VISIT – ADDITIONAL PROCEDURES IF BASELINE VISIT IS DONE IN THE CRC

If the baseline visit is in the CRC, you will arrive at the CRC fasting meaning nothing to eat or drink (except for water) for at least 10 hours prior to your visit to prepare for the collection of blood samples. Additionally, you will be asked not to eat or drink (except for water), chew gum, smoke, brush your teeth, exercise physically, or consume prescription or over-the-counter medications in the 60 minutes prior to the baseline visit (as well as during the last 60 minutes of the baseline visit) to prepare for the collection of saliva samples. You will be asked not to wash your hair for 24 hours before the baseline visit, and not to have your hair cut to a length less than 2 cm, to prepare for the ***optional*** collection of 2 cm hair samples. You will be asked not to clip your fingernails for at least 2 to 3 weeks prior to the baseline visit to prepare for the ***optional*** clipping of approximately 2 mm of nails from each finger of both hands. You will be asked to remove any nail polish at least 24 hours before the baseline visit. You may opt-out of providing hair and/or nail samples at the end of this consent form, and will still be permitted to continue in the study.

If the baseline visit is in the CRC, a single sample of approximately 4 tablespoons (60 mL) of blood will be drawn fasting. The blood will be analyzed immediately for hemoglobin A1c, and other common blood tests to determine your health status including fasting glucose, cholesterol and high sensitivity C-reactive protein (a measure of inflammation that can be used to determine your risk for heart disease). The remainder of the blood will be frozen to be analyzed later under this study for additional measures of inflammation, and fasting c-peptide (a measure of how much insulin is being made by your pancreas). Insulin is a hormone that manages your blood sugar. Within 5 minutes of having your blood drawn, you will be asked to obtain a glucose reading from your continuous glucose monitor if you use one, and a small finger stick sample of blood to test your blood glucose on your glucometer and your hemoglobin A1c on the Home A1cNow Self Check Kit provided to you at your screening or baseline visit. Research staff will compare glucose readings from the different sources to assess the accuracy of your devices, and will notify you of discrepancies once the reference laboratory glucose result is obtained.

If you give permission for storage of your leftover samples for future research studies which is described at the end of this consent form, some of your saliva, hair and nail samples may be used for testing levels of the stress hormone cortisol and other hormonal and metabolic parameters. Once the research is completed, your leftover research specimens will be discarded unless you agree to have them stored and used for future research studies.

If the baseline visit is in the CRC, you will undergo a brief physical exam, including blood pressure, pulse, body weight, height, and waist and hip circumference. Body composition will be measured with a Tanita scale when possible. The Tanita scale uses advanced Bioelectrical Impedance Analysis technology. When you stand on a Tanita scale, a very low, safe electrical signal is sent from four metal electrodes through your feet to your legs and abdomen. The electrical signal passes quickly through water that is present in hydrated muscle tissue but meets resistance when it hits fat tissue. The Tanita scale measures this resistance, known as impedance, and uses it to calculate body composition measurements including the percentages of body fat and muscle. If you have an electronic medical implant, such as a pacemaker, we will not use the Tanita scale because the electrical signal traveling through the body may interfere with the operation of your electronic medical implant. The Tanita scale can be safely used during pregnancy, but it will not give an accurate reading.

RANDOMIZATION Phone Call (Study group assignment)
After the baseline visit, you will receive a Randomization phone call from a member of the study team who will randomly assign you to one of two study groups for 6 months. The two study groups are two different live online stress reduction programs, one of which is combined with health education. Being

randomly assigned to the study group means that whichever study group you are assigned to will be determined purely by chance, like flipping a coin. You will have a 1 out of 2 chance of receiving any of the following study stress reduction programs:

Arm 1: Stress Reduction
Arm 2: Stress Reduction with Health Education

If for some reason you are not able to be randomized within the required study time frame, you will have the opportunity to repeat your screening and baseline visits at a later date, provided you still qualify for the study.

This Randomization phone call will take place in the week before the Orientation session. During the Randomization phone call, you will be given information about your classes, including your instructors' names and contact information, the PSU Zoom link for your classes, and the dates and times of your classes.

Once you are assigned to a stress reduction group, you will participate in the following 14 study sessions online in a live interactive virtual classroom using video-conferencing (PSU Zoom):

- Orientation: This is one session that will last 1 and a half to 2 hours. You must attend Orientation to continue in the study. If you miss the Orientation session you will not be able to continue in the study.
- Class #1 to 8: These are eight sessions. These sessions will occur once a week for eight weeks after Orientation. Each of these sessions will last 2 and a half to 3 hours.
- Retreat: This is one session that will last 7 hours.
- Booster sessions #1 to 4: These are four sessions. These sessions will occur once a month in Months 3, 4, 5, and 6. Each Booster will last 45-minutes.

During these study sessions, you will be asked to participate in one or more of the following activities: breathing exercises, meditation, stretching exercises or health education activities. Study sessions will consist of small groups of up to approximately 15 to 20 participants. Each session will be led by an instructor. During the study, you will be asked to spend at least 25 to 30 minutes a day for six out of seven days per week, outside of the sessions, doing home practice including reviewing the materials covered in the sessions, practicing activities related to your study sessions, or listening to excerpts of audio books. You will be given home practice assignments for the first seven weeks, starting after Class #1. There will be no home practice assignments after Class #8, however after Class #8 you are encouraged to continue your home practice activities regularly on your own. After Class #1, the email survey you receive once a day will ask you questions about your daily home practice, in addition to your stress level and food cravings.

Adherence to the study sessions you are assigned to is very important in this study. If you cannot commit to the study sessions with reasonable certainty, you will not be enrolled. Attendance will be recorded at each session. It is possible that for some unforeseen reason you miss a session. If this happens, you may not be able to make the session up, but you will be encouraged to continue to follow along with the home practice and do your best to attend all the remaining sessions that you are assigned to.

During the follow-up phone call, study visits, and any other contact with the research coordinators or members of the study team (other than the instructors), you will be asked not to say anything that could reveal your group assignment, such as:

- Your instructors' names

- The PSU Zoom link for your classes
- Your home practice questions
- Any other specifics about your classes

This is because the research coordinators and other members of the study team (other than the study instructors) will be blinded, meaning they will not know which study group you are assigned to.

During the study, you will continue to receive usual care from your physicians, regardless of the study group you are assigned to. It is expected that you will be on medical treatment for your diabetes as prescribed by your physician, and you will be advised to follow-up with your physician every three months to ensure that you are on optimal medical treatment. If you are currently on any medications, you should not change or discontinue any of your medications during the study unless directed to do so by your physician. During the study, you will be encouraged to continue your routine activities, and you will be instructed not to participate in any other formal stress reduction programs during the six months that you are in the study.

FOLLOW-UP PHONE CALL AFTER CLASS #4 (VISIT #2)

You will receive a phone call from the research coordinator within 2 weeks after Class #4 during which you will be asked questions about stress-related symptoms and low blood glucose. You will be reminded not to say anything that could reveal your group assignment during this phone call because the research coordinators will be blinded, meaning they will not know which study group you have been assigned to.

2-MONTH VISIT (VISIT #3) & 6-MONTH VISIT (VISIT #4/FINAL VISIT)

The 2-month visit will be scheduled after Class #8, and the 6-month visit will be scheduled after Booster #4. These visits will be scheduled via video-conferencing or at the CRC. During these visits, the procedures described above in the baseline visit will be repeated. The study personnel that you meet during the 2-month visit and the 6-month visit will be blinded, meaning they will not know which study group you have been assigned to. So you will be asked not to say anything to them that could reveal your study group assignment. It is important that you come in for these visits regardless of the study group that you are assigned to. Your participation in these visits will be very important to the success of the study.

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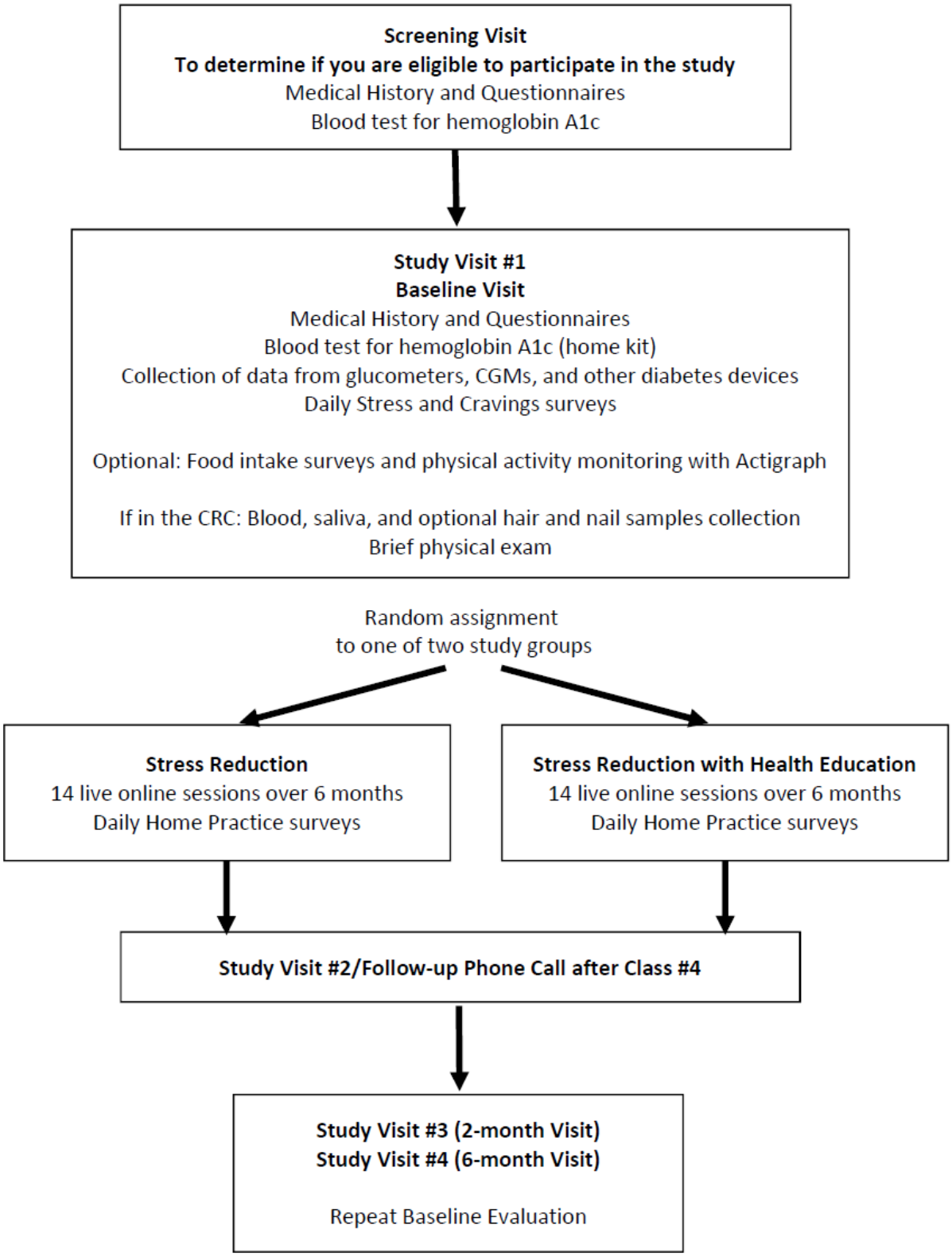
The following flow chart is an overview of what will happen in this study:



3. What are the risks and possible discomforts from being in this research study?

Risks of Stress Reduction Programs
Stress reduction programs have been used in a variety of patient populations, including patients with serious medical illnesses. There is a risk of increased distress with stress reduction programs due to greater awareness of stress. Potential risks include: increased depression, anxiety or panic, re-experiencing of traumatic memories [especially if there is a history of trauma or post-traumatic stress disorder (PTSD)], headaches, body pain, unable to sleep (insomnia), feeling disconnected from everything around you (dissociation) and unable to think clearly and/or make decisions (executive dysfunction). To minimize these risks, we will use trained instructors and monitor your levels of distress during the study.

Risks of Exercise
During the study sessions you may be asked to perform gentle stretching and other light exercises. There are risks inherent to any exercise program. Such risks include, but are not limited to, risk of slip, trip, fall, and bodily injury. The instructors will work with you to minimize these risks.

Risks of Low Blood Glucose
If you are on certain diabetes medications, such as insulin or a sulfonylurea, you may be at risk for low blood glucose (hypoglycemia or blood glucose less than 70 mg/dL) during or after the stress reduction sessions or home practice due to the effects of stress reduction or exercise on your blood glucose. Regardless of the medications you are on, you are advised to check your blood glucose before and after each stress reduction session and home practice (and during long or intense stress reduction sessions or home practice). You are advised to carry the following items with you at all times, including at your study visits and stress reduction sessions: your glucometer, testing supplies, and carbohydrate-rich foods such as juice, hard candies or glucose tablets to treat low blood glucose, if it occurs. If you have glucagon, you are advised to also carry it with you at all times. You will be provided written guidelines about how to monitor for, treat, and prevent low blood glucose. You are advised to ask your physician for instructions on adjusting your diabetes medications, if needed, when participating in stress reduction sessions or doing home practice.

Signs and symptoms of low blood glucose may include:

- Headache
- Nervousness or feeling anxious
- Weakness
- Dizziness or light-headedness
- Confusion
- Sleepiness
- Irritability
- Hunger
- Fast heartbeat
- Sweating
- Feeling shaky or jittery
- Loss of consciousness if left untreated

You are advised to have 911 called if you ever have severe hypoglycemia, which is when you are having symptoms that are keeping you from being able to treat hypoglycemia yourself and you require the assistance of another person to treat your hypoglycemia. You are advised to contact your physician and the study team if you ever have a glucose less than 54 mg/dL or hypoglycemia requiring the assistance of another person to treat. You are advised to contact your physician if your blood glucose level ever drops below your goal during the night or upon awakening, or if your blood glucose level frequently drops below your goal at other times of the day.

Risks of Fasting
The risks of fasting include feeling light-headed, dizzy or faint. If you are on certain diabetes medications, such as insulin or a sulfonylurea, you may be at risk for low blood glucose while fasting for the study visits, and your medications may need to be adjusted when you are fasting. You are advised to ask your physician for instructions on adjusting your diabetes medications, if needed, while fasting.

Risks of Venipuncture
The discomfort associated with removing blood by venipuncture (by needle from a vein) is a slight pinch or pin prick when the sterile needle enters the skin. The risks include mild discomfort and/or a black and blue mark at the site of puncture. Less common risks include a small blood clot, infection or bleeding at the puncture site, and on rare occasions fainting during the procedure. To minimize discomfort from blood sampling, the amount of blood we will remove will be 4 tablespoons or less.

Risks of Randomization
You will be assigned to one of two different stress reduction programs by chance. The study stress reduction program you receive may prove to be less effective or to have more side effects than the other study stress reduction program or other available treatments.

Risks of Loss of Confidentiality
There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

During the study stress reduction sessions, all participants will be instructed to keep all conversations occurring during the sessions completely confidential. You are not required to answer any questions or reveal any information that you do not want to.

Risks of Questionnaires
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Risks of High Blood Glucose
The study stress reduction programs are not expected to increase your blood glucose levels. However, it is possible that in the process of collecting your glucose data from your glucometers, CGM and other diabetes devices, we become aware of hyperglycemia (increased blood glucose level). You will be provided written guidelines about how to monitor for and prevent hyperglycemia. You are advised to contact your physician if your blood glucose levels are persistently elevated above your goal. In the event of severe hyperglycemia (blood glucose level persistently over 350 mg/dL), you will be referred to the Emergency Department at Milton S. Hershey Medical Center, or your local Emergency Department, for immediate evaluation.

Unforeseen Risks
There may be unknown risks or risks that we cannot predict associated with being in this research. It is possible that the study procedures could detect a possible unknown medical problem that is unrelated to the purpose of this study. If the research procedures uncover findings that may be important for you to know about, such as the possibility of a previously unknown medical condition, a member of the study team may contact you to find out if you would like to learn more. These findings may require

additional testing or treatment. The cost of any additional tests or related treatment will be your responsibility.

The Data and Safety Monitoring Board (DMSB), an independent group of experts, will be reviewing the information from this research throughout the study. If any important new information about the study develops that may affect your health, welfare, or willingness to stay on the study, your study doctor will tell you. You may be asked to sign another consent form at that time.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include reduced stress, improved quality of life and overall well-being, and possibly better blood glucose control. If you are assigned to the stress reduction with health education group, you may benefit from education about nutrition and exercise.

4b. What are the possible benefits to others?

The results of this research may guide the future treatment of diabetes. The knowledge gained from the proposed study may help researchers to develop effective comprehensive treatment programs for patients with diabetes that address both the mind and the body to reduce stress, improve blood glucose control and other key health outcomes, and optimize overall health and wellbeing in patients with diabetes.

5. What other options are available instead of being in this research study?

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive commercially available treatments, including medications used to treat diabetes, as well as Diabetes Education, medical nutrition therapy, counseling, and other exercise or stress reduction program, after talking with your physician.
- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition, after talking with your physician.

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

The stress reduction programs offered in this research are available to you without taking part in this research study.

6. How long will I take part in this research study?

If you agree to take part, it will take you about six to eight months to complete this research study. During this time, we will ask you to complete one screening visit via video-conferencing or in the CRC, one follow-up phone call, three study visits via video-conferencing or at the CRC, and 14 live online study sessions via video-conferencing.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal

information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

In our research files at Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: your name, address, email address, phone numbers, date of birth, medical record number, social security number (which will be used for payment purposes), and a code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Raja-Khan's research office.
- Your research records will be labeled with your code number, your initials, and your date of birth, and will be kept in a safe area in Dr. Raja-Khan's research office.
- Your research samples will be labeled with a code number, and date of collection and will be stored in secured freezers in the Penn State Institute for Personalized Medicine.
- A copy of this signed consent form will be included in your PSH medical record. This means that other PSH healthcare providers will know you are in this study.
- Results of some of the research-related clinical tests (including but not limited to hemoglobin A1c) will be kept in your PSH medical record.

For research records and specimens sent to the University of Virginia Core Ligand Lab, you will be identified by your code number and date of collection.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to the National Institutes of Health in order for it to evaluate or audit the research, or prevent disclosures required to meet FDA requirements. For additional information ask the principal investigator or a member of the study team or contact the Human Subjects Protection Office at (717) 531-5687.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. What will happen to my research information and/or samples after the study is completed?
Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies. They share this information with each other by putting it into scientific databases. Your coded research information may be put in one or more databases and used for future research. Your information stored in these databases will not include any

identifying information such as your name, address, telephone number, or social security number. Your research data will only be available to researchers who have received approval from data access committees and/or Institutional Review Boards. Some of these databases are maintained by PSH/PSU, some are maintained by the federal government, and some are maintained by private companies and other institutions.

7c. How will my identifiable health information be used?
In general, under federal law (including the Health Insurance Portability and Accountability Act – HIPAA or privacy laws) your health information is private. By signing this form, you are authorizing us to collect, use, and disclose your identifiable health information, sometimes referred to as "Protected Health Information" or "PHI" under HIPAA, for the purposes of this research study. We will use and disclose your information only as described in this form, in the PSH Privacy Notice, and as may be required or allowed under the applicable privacy laws.

The research team may use the following health information:

- Past, present, and future medical records, including identifiable information
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- PSH/PSU research staff involved in this study
- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Subjects Protection Office
- The PSH/PSU Research Quality Assurance Office
- Non-research staff within PSH/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- The sponsor(s) of this study, monitors and auditors, and other people or groups it hires to help perform this research
- Other researchers and medical centers outside of PSU and Penn State Health that are part of this study and their IRBs
- Researchers from other campuses of Penn State University who are part of this study
- A group that oversees the data (study information) and safety of this research
- The Core Ligand Lab at the University of Virginia

These groups may also review and/or copy your original PSH/PSU records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We

share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable health information and samples may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify Dr. Raja-Khan (who is the principal investigator in charge of this research study) by calling 717-531-8395 or by writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You will be sent a formal notification when you are deemed withdrawn or lost to follow-up, or when you have completed the study. Upon this notification (either in-person, via phone, or via email), you will receive instructions from the study team outlining how to disconnect all applicable remote data transmissions (e.g. Dexcom Clarity, LibreView, etc.). If for any reason you are unable (or unwilling) to successfully follow the disconnection instructions, your data may continue to be transmitted to the research team. If this happens, the research team will not use any data that is transmitted after the date that you are no longer considered an active participant of the study.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are <u>only</u> being done for the research study:

- The study stress reduction sessions will be provided by the National Institutes of Health at no cost to you while you take part in this study.

- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.

The research-related tests and procedures that will be provided at no cost to you include: blood work, pregnancy tests, saliva tests, collection of hair and nail samples.
For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?
It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

<u>PSH/PSU compensation for injury</u>

- There are no plans for PSH/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?
You will receive $25 for completing the screening visit, $35 for completing the baseline study visit, $50 for completing the 2-month study visit, and $70 for completing the 6-month study visit.

Additionally, you will receive up to $105 for completing 14 stress reduction sessions as $5 per session for the first 5 sessions you attend, $8 per session for the next 5 sessions you attend, and $10 per session for

the next 4 sessions you attend. The money for completing the stress reduction sessions will be given to you at the 2-month and 6-month study visit.

You will also receive an additional $15 if you complete at least 70% of the Stress and Cravings and Daily Home Practice surveys by your 2-month study visit.

The total amount you will receive for your participation in this research study is up to $300. If you do not complete the study for any reason, you will be paid for the study visits and stress reduction sessions you have completed. The payment will be provided by Greenphire Clincard.

This reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the $5 replacement fee.

When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, and Social Security Number.

You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your Mobile Phone Number and/or E-mail Address.

Payment received as compensation for participation in research is considered taxable income. If payments from Greenphire exceed $600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of Penn State.

It is possible that your research information and/or specimens (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Institutes of Health to support this research.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked to explain the extent of your withdrawal, including whether you wish to withdraw from the study stress reduction sessions, but agree to continue to undergo the follow-up procedures and data collection. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

Your research doctor may take you out of the research study without your permission.

- Some possible reasons for this are: continuing the research would be harmful, your condition has become worse, you become pregnant, you did not follow the instructions of the study doctor, you experience serious side effects.
- Also, the sponsor of the research may end the research study early.
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Nazia Raja-Khan at (717) 531-8395 or the Endocrinology doctor on 24-hour call at (717) 531-8521 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the Human Research Protections Program (HRPP) at (717) 531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HRPP at (717) 531-5687.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

Optional part(s) of the study

In addition to the main part of the research study, there are other parts of the research. You can be in the main part of the research without agreeing to be in these optional parts.

Optional collection of food intake surveys and Actigraph physical activity data

You should initial below to indicate if you give permission to provide food intake data.

I agree to complete ASA24 surveys to provide food intake data.

_____ Yes _____ No

You should initial below to indicate if you give permission to provide physical activity data.

I agree to wear the Actigraph to provide physical activity data.

_____ Yes _____ No

Optional collection of hair and nail samples (not applicable for remote visits)

You should initial below to indicate if you give permission to provide hair samples.

I agree to provide hair samples.

_____ Yes _____ No _____ N/A (study visits will be remote)

You should initial below to indicate if you give permission to provide nail samples.

I agree to provide nail samples.

____ Yes ____ No _____ N/A (study visits will be remote)

Optional storage of tissue for future research (not applicable for remote visits)

In the main part of this study, we are collecting blood and saliva samples from you. In an optional part of the study, if you give permission we are collecting hair and nail samples from you. If you agree, researchers would like to keep your leftover sample(s) and health information for future research studies. These future studies may be helpful in understanding diabetes and related disorders. Some of the blood samples may be used to measure levels of cortisol (stress hormones) and inflammatory markers (proteins in the blood that are a marker for inflammation and heart disease risk).

- Your leftover samples will be labeled with a code number and date of collection.
- These samples will be stored in secured freezers in the Penn State Institute for Personalized Medicine.
- The length of time they will be used is unknown.
- You will be free to change your mind at any time.

• You should contact Dr. Raja-Khan at 717-531-8395 and let her know you wish to withdraw your permission for your blood and saliva to be used for future research. Any unused blood and saliva will be destroyed and not used for future research studies.

Storage and Sharing of Research Data for Future Research

Researchers can do studies that are more powerful when they share with each other the data or information they get from studying human samples. They share this information with each other by putting it into scientific databases. There are different kinds of databases. Some are unrestricted-access databases (publicly accessible), which anyone on the internet can obtain information. Others are controlled-access databases which are available only to researchers who have received approval from data access committees. Some of these databases are maintained by Penn State College Medicine (PSU) and The Milton S. Hershey Medical Center (HMC), some are maintained by the federal government, and some are maintained by private companies and other institutions.

Anonymous genetic and health information from the analyses of your samples may be put in one or more of the unrestricted-access databases. This information will be used for future research. Your name and other information that could identify you will not be included in the database. Therefore, no one would know just from looking at the data that the information came from you.

Your coded genetic and health information may be put in one or more of the controlled-access databases and used for future research. Your information stored in these databases will not include any identifying information such as your name, address, telephone number, or social security number. We will replace this identifying information with a code number. We will keep a master list that links your code number to your identifying information here at Penn State College of Medicine (PSU) and the Hershey Medical Center (HMC). Only certain research staff members at HMC/PSU will have access to this master list.

Results of Future Research

- You should not expect to get personal results from the future research done on your samples and information. Researchers will study samples and information from many people; it will take many years before they know if the results have any meaning. There is also a small chance that researchers could find something that might be important to your health. If this happens, researchers may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in future research?

• Agreeing to have your PHI and medical record information matched with your samples and research results means that there is the potential for the release of this information. However, the chance that this information would be released is extremely small because the research team will use many of the same safeguards that your doctor and other providers use to keep your medical information private in order to protect your research information to the full extent permitted by law.

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- Risks of the storage in unrestricted-access and controlled access databases
  - There is a risk that someone in the future could link your genetic or medical information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse, but they may not give full protection.
  - It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may be other unforeseen privacy risks.
  - We believe the chance these things will happen is very small, but we cannot guarantee that your identity will never become known. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them.
  - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes.
  - There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

What are the possible benefits from being in future research?

• It is unlikely that future research studies will have a direct benefit to you. However, the results of the future research may help doctors and scientists make discoveries that may help people in the future.

Will I be paid to take part in future research?

•You will not receive any payment or compensation for being in future research.

•Your extra blood, saliva and leftover samples you donate will not be sold but will be used exclusively for research. However, the research may lead to a discovery that could be patented or licensed and may lead to new tests, drugs, or other commercial products in the future, which have commercial value. No financial compensation will be provided to you if this occurs. Any financial benefits to Penn State will be used for research and non-profit public benefit purposes.

You should initial below to indicate what you want regarding the storage of your leftover blood and saliva for future research studies.

a. Your sample[s] may be stored and used for future research studies to learn about, prevent, treat or cure diabetes.

_____ Yes _____ No _____ N/A (remote visit)

b. Your sample[s] may be stored and used for research about other health problems.

_____ Yes _____ No _____ N/A (remote visit)

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c. Your sample[s] may be shared with other investigators/groups without any identifying information.
_____ Yes _____ No _____ N/A (remote visit)

I will allow researchers to invite me for future research studies. Penn State researchers may have additional questions from their studies and may wish to contact you for further information or to participate in other research projects. Initial below to indicate what you want regarding contact for future research studies.

Penn State researchers may contact me for additional information on this study.
_____ Yes _____ No

Penn State researchers may contact me for future research studies.
_____ Yes _____ No

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the optional part(s) of the research to the subject or subject representative and have answered any questions the subject or subject representative has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

Signature of Person Giving Informed Consent

Signature of Subject

By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part(s) of the research study.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name