Protocol Title: Diabetes Prevention in Women with a Recent History of GDM

Principal Investigator: Ellen Seely, M.D.

Site Principal Investigator: Ellen Seely, M.D.

Description of Subject Population: Postpartum women with gestational diabetes in most recent pregnancy

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

We would like to ask you to take part in a research study. We are doing this research study to test whether a lifestyle program, designed specifically for women like you with a recent history of gestational diabetes mellitus (GDM), will help women lose weight gained during pregnancy and to reduce risk factors for developing type 2 diabetes. Many studies have shown that women with a history of GDM have a higher risk of developing type 2 diabetes within 5 to 15 years after pregnancy than women who do not have a history of GDM. We have modeled this lifestyle program on a large federally-funded study called the Diabetes Prevention Program (DPP). The DPP showed that a lifestyle program focusing on healthy eating and physical activity led to less type 2 diabetes in men and women at high risk. This study will test whether a lifestyle program delivered during the two years (24 months) after giving birth will lead to a reduction in risk

factors for type 2 diabetes, including the loss of weight gained during pregnancy in women with a recent history of GDM.

We are asking you to take part in this research study because you had GDM in your most recent pregnancy. A total of about 250 subjects, ages 18 to 45, will take part in this study at Brigham and Women's Hospital.

It is important that you read the following information before signing your name to the final page and enrolling in this study. You should discuss any questions or concerns about taking part in this study with the study doctor.

All of the procedures to be performed in this study are being done only for research purposes. They are not designed to take the place of your usual medical care. However, laboratory tests and other diagnostic tests will be performed on you during the study. This information will be made available to your primary care physician and OB unless you decline this option. If these results are given to your physician(s), they will become part of your clinical record. We will also be asking for your permission to view your medical records, as well as your infant's medical records.

The Centers for Disease Control and Prevention (CDC) is paying for this research to be done.

How long will I take part in this research study?

If you sign this form, you will be agreeing to take part in this study for 24 months after your delivery. During this time, we will ask you to come to 5 study visits, 3 of which will each take about 3 hours, and 2 of which will each take about 1 hour.

What will happen in this research study?

If you agree to participate in this study, you will be assigned by chance (like a flip of a coin) to one of two groups: the lifestyle group or the Post-GDM Follow-up group at your first study visit (around 6 weeks after delivery). You and the study doctor will not be able to choose your study group.

Women in both groups will be asked to come to five study visits at the BWH, one at 6 weeks after delivery, another at 6 months after delivery, another-at 12 months after delivery, another at 18 months after delivery, and the last one at 24 months after delivery. We will call you to remind you about each appointment. If there are conflicts with these dates, we can schedule your 6 week

visit any time during 4-10 weeks postpartum. We can schedule your 6 month, 12 month, 18 month and 24 month visits within four weeks before or after the actual date.

At three of the study visits (6 weeks after delivery, 12 months after delivery, and 24 months after delivery), the following will happen:

- You will be scheduled at one of three sites within the Center for Clinical Investigation at Brigham and Women's Hospital, depending on your childcare needs:
  - Clinical Trials Center
  - Ambulatory Care Center
  - 9A clinic
- If you decide to bring your children, we will book you at the CTC or ACC as 9A does not allow children in the clinic. We encourage you to bring a family member or friend to watch over them. If you do not bring someone with you to watch your child(ren) you may also you may bring your child(ren) into the room with you. However, you will not be allowed to breastfeed during the first two hours of testing.
- The study staff will measure your height, weight, waist size, and blood pressure.
- *Oral Glucose Tolerance Test:* On this morning, you will have an oral glucose tolerance test (OGTT). We use this test to find out how well your body uses up glucose (sugar), which is produced when your body digests food. This test is used to diagnose diabetes. After fasting (going without food or drink, anything but water) overnight, we will ask you to drink 75 grams (about 1 cup) of carbohydrate soda ("glucola"). This is the same sugar drink you received during your pregnancy to test for gestational diabetes, but the amount is less than that used in pregnancy. During your visit, you will receive two needle sticks, one to collect fasting blood samples before the OGTT begins and a second 120 minutes (2 hours) after drinking the glucola to measure your glucose and insulin levels.
- We will take up to 60 cc (about 4 tablespoons) of blood total to measure levels of glucose (sugar), insulin (a hormone that regulates blood glucose levels), blood fats, HbA1c (marker for type 2 diabetes), adiponectin and CRP (two markers of diabetes and heart disease risk), and a biomarker to predict blood glucose.
- During the OGTT, we will ask you to complete a study questionnaire that will take approximately 40 minutes to complete. The questionnaire will tell us about your current diet, physical activity levels, mood, and perceived stress. You can skip any questions you choose not to answer. Your answers to this questionnaire will be not shared with anyone outside of the study staff.
- The study visits will each take approximately 3-4 hours.
- At each study visit, you will get a snack before you leave.

At the other two study visits (6 months after delivery and 18 months after delivery), we will not do an OGTT but all of the other procedures will remain the same. You will be scheduled at one of the same three sites at the BWH. You are welcome to bring your child(ren). Study staff will

measure your height, weight, waist size, and blood pressure. During your visit you will receive one needle stick where we will take up to 40 cc (about 3 tablespoons) of blood total to measure levels of glucose (sugar) and HbA1c (marker for type 2 diabetes).Lastly we will ask you to complete a shortened study questionnaire asking about your current diet and physical activity levels. The study visits will each take approximately 1 hour.

In addition to all of the above, you will be asked to take a urine pregnancy test at the 6 month, 12 month, 18 month, and 24 month study visits. If you become pregnant during the study, you can no longer participate in the study. We will, however, ask your permission to obtain your medical records for the pregnancy.

Remember that you will be assigned by chance (like a flip of a coin) to either the lifestyle group or the control group at your first study visit, around 6 weeks after delivery. The study procedures for the lifestyle group and control group are described below.

Lifestyle Group: If you are assigned to the lifestyle group, you will take part in an internet-based lifestyle program, which has been designed specifically for new mothers like yourself. Lifestyle subjects will need a computer with internet access to take part in this group. All lifestyle subjects will be loaned a computer at their first study visit, if they need one. Internet access will be arranged for those subjects who do not already have internet access. Subjects will be asked to return the computers at the end of the study.

If you are assigned to the lifestyle group, the lifestyle program will begin at your very first study visit (about 6 weeks after delivery) with a one on one introduction to the internet-based program by the Lifestyle Coach. This lifestyle program includes 12 weekly internet-based sessions held over a period of 12 weeks, led by a Lifestyle Coach who is a trained dietitian. Each session will take about 15-30 minutes. Each of the sessions is designed with new mothers like yourself in mind, to help you with healthy eating, engaging in physical activity, and problem-solving to overcome barriers you might experience in reaching your healthy eating and physical activity goals.

Lifestyle group subjects will be invited to two in-person group session presentations that will take place within the first few weeks of the study at Brigham and Women's Hospital. These group meetings will offer subjects in the lifestyle group the opportunity to meet face to face with other women in the study. Recorded versions of these sessions will posted online for all women who cannot come to in-person sessions.

For the first year (12 months) of the study, you will have access to the Lifestyle Coach for personal help modifying your diet, increasing your physical activity levels, and problem-solving potential barriers that may prevent you from reaching your goals (diet and physical activity). You will have telephone contact with the Lifestyle Coach at least once a week**.** These phone

conversations may be recorded as data for the study. We will ask for your permission to start the recorder at the beginning of the call. Your name will not be associated with your recordings. The recordings will be labeled with a code and stored on a password-protected computer drive, to which only study staff have access. You may have more contact if you or the Lifestyle Coach decides that you need more contact to help you to maintain or reach your goals. The Lifestyle Coach will be available to talk with you about healthy food choices, problems with meeting your physical activity and healthy eating program goals, and possible ways to overcome the challenges you may face in keeping on track.

In addition to the Lifestyle Coach, you will have the chance to get extra support for your lifestyle goals through interacting with the other new mothers with recent GDM assigned to the lifestyle group. You will be able to become a member of an on-line community where you can both give and receive support to/from other new mothers like yourself. You will have access to a secure blog where you can post questions to the group and communicate on-line with other new mothers. In addition, for the first year of the study, you can use the website to communicate directly and privately with your Lifestyle Coach.

During the second year of the study you will still be able to access the internet-based lifestyle intervention and the secure blog to communicate with other new mothers with recent GDM. However, after the first 12 months of the study you will no longer have access to the Lifestyle Coach. This is so we can learn whether the lifestyle program can be maintained without the personal support provided by the Lifestyle Coach.

You will also be asked to keep track of a) your physical activity by writing down the number of minutes of physical activity you do each week; and b) the foods you are eating every day. You will write down this information in a Physical Activity Log book and Food Diary given to you by the study staff. In addition, subjects in the lifestyle group will receive a pedometer, a small tool that helps you counts the number of steps taken, to help keep track of and reach physical activity goals. You will also be asked to respond to a weekly email about the food you ate and the physical activity you did that week.

Post-GDM Follow-up Group: As discussed above, if you are assigned to the control group, you will have the same 5 study visits as the women assigned to the lifestyle group: including OGTTs and laboratory tests and will fill out the same study questionnaire at 6 weeks, 6 months, 12 months, 18 months, and 24 months after delivery.

Leaving the Study Early

You may decide to stop the study at anytime. If you withdraw from the study before it is completed, you are asked to speak with the study staff about your decision to leave the study.

Also, we may stop you from taking part in this study if: the study doctor thinks it is unsafe for you to continue in study; you develop a condition that makes it impossible for you to continue in the study; or if your lab tests are abnormal.

Storing Samples and Health Information at BWH for Future Use

We would like to store some of your samples and health information for future research related to gestational diabetes, diabetes, weight loss, and/or other related health concerns. We will label your samples and health information with a code instead of your name. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a locked file.

Do you agree to let us store your samples and health information for future research related to gestational diabetes, diabetes, weight loss, and/or other related health conditions?

☐ Yes ☐ No Initials_____

If later you change your mind and want your samples destroyed, contact the study doctor.

We may have future studies that you would like to take part in.

Would you like to hear about future studies?

☐ Yes ☐ No Initials_____

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

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

Blood Draws

Placing a needle into a vein in your arm may cause a bruise and/or bleeding. The bruise may last for a day or so. Occasionally a person feels faint when blood is drawn.

The total amount of blood drawn throughout the entire study period is about 18 tablespoons. The withdrawal of this amount of blood over a period of several months would not be expected to cause any symptoms or have any medical consequences.

Oral Glucose Tolerance Test

The glucose solution ("glucola") has a very sweet taste, and may possibly cause nausea, or, rarely, vomiting.

Questionnaire

The questionnaire may be tiring to fill out or make you feel uncomfortable, but you will be given as much time as you need to complete it. Also you can skip any questions you feel uncomfortable answering.

Weight Loss

If you lose weight too fast, you might feel weak or fatigued. The lifestyle program is designed for gradual and safe weight loss overseen by the Lifestyle Coach, a trained dietitian.

Other Risks

There may be other side effects or risks, in addition to those described in this document, that are not known at this time. We will give you any new information that we learn during the course of the study. This new information might affect your willingness to be in or stay in the study.

The study staff and doctors working on this study will monitor you closely during your time in the study and have years of experience performing the non-invasive study procedures, so the anticipated risk to all subjects from this study is minimal.

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

You may receive no direct individual benefit from participating in this study. This study will try to see if a lifestyle program modeled upon the DPP designed for women in the first year after a GDM pregnancy can cause healthy diet and physical activity changes in their lives that lead to

weight loss and lower risk for future development of type 2 diabetes. We think the things we learn in and from this study will help future lifestyle programs for women, especially new mothers, be successful and lead to a better understanding of women's health in general.

Study doctors will review the results of all clinical procedures done at the 5 study visits, which might identify problems, like development of type 2 diabetes. If your study tests suggest illness or disease, the study doctor may elect to repeat the test for confirmation. If the repeat test confirms the diagnosis the study doctor will explain the findings to you and refer you to your doctor for follow-up care. And so, you could benefit from earlier treatment than if you were not taking part in this study.

What other treatments or procedures are available for my condition?

Women with a history of gestational diabetes can engage in a healthy lifestyle outside of this study. An OGTT may be performed by your regular doctor around 6 weeks after delivery as part of routine care. If you have any further questions about gestational diabetes, please talk to your doctor.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

Total compensation for your 6-week visit is $100, of which you will receive $25.00 in cash for childcare or transportation needs. Upon completion of the study visit, you will receive a check for $75.00 within 4-6 weeks. You will receive the same amounts in cash and by check following your 12 month visit. Total compensation for your 6-month visit is $80, of which you will receive $20~~5~~.00 in cash for childcare or transportation needs. Upon completion of the study visit, you will receive a check for $60.00 within 4-6 weeks. You will receive the same amounts in cash and by check following your 18 month visit. Total compensation for your 24-month visit is $140.00, of which you will receive $25.00 in cash for childcare or transportation needs. Upon completion of the study visit, you will receive a check for $115.00 within 4-6 weeks. You will have the option of receiving all remuneration by check.

Upon completion of the required study visits, you will have received a total of $500.00. If you have not received your compensation within 8 weeks of your final study visit, please contact Lucia Joseph at 617-732-8538 or ljoseph7@partners.org.

We will pay for the costs of parking at all study visits.

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

Although study funds will pay for certain study-related items and services, we may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Ellen Seely is the person in charge of this research study. You can call her at 617-732-5012 Monday-Friday 9-5. A study staff member will be available to reach 24 hours a day, seven days a week at beeper #32225.

If you have questions about the scheduling of appointments or study visits, call Lucia Joseph at 617-732-8538.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you

should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review 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)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not

use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't 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 the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: March 2015