Joslin Diabetes Center

Committee on Human Studies

Informed Consent & Authorization Form

Participant's Name: _____

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

Principal Investigator: Florence M. Brown, M.D.

Co-Investigator(s): Tamarra James-Todd, Ph.D. M.P.H, Jo-Anne Rizzotto, R.D., C.D.E., Suzanne Ghiloni, R.N., B.S.N., C.D.E., Elizabeth Halprin, M.D., Shanti Serdy, M.D., Allison Cohen, M.D., Ann Goebel-Fabbri, Ph.D., Susan Herzlinger, M.D., Jacqueline Shahar, MEd, RCEP, C.D.E., Ashley Curran B.Sc.

Study Title: Barriers to Adherence to Recommended Follow-up in Women with a History of Gestational Diabetes

Study Sponsor: Roche Diagnostics

Study Contact: Florence M. Brown, M.D. at 617-309-2496

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

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

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

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

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

Purpose of Study

You have been asked to participate in this study because you were recently diagnosed with gestational diabetes.

The purpose of this study is to find out whether women who have had gestational diabetes will make healthier lifestyle choices, achieve weight goals and complete postpartum care assessments after receiving education on healthy nutrition and exercise.

The study will involve about 30 women.

This study is being funded by a grant from the pharmaceutical company, Roche Diagnostics. Roche Diagnostics is a division of the Hoffmann-La Roche Company and they manufacture healthcare tools and reagents including diabetes monitoring equipment.

Study Procedures

Enrollment/Randomization
This visit will occur during your 3rd trimester of pregnancy (28-40 weeks) or up to 3 months after you deliver your baby. This visit will take about 20 minutes.

At this visit a member of the study team will review the study with you and determine if you are eligible to participate. If you are eligible and want to participate you will be randomized (like the flip of a coin) to one of three study groups. You will not get to choose which group you are in.

- Group One - Standard postpartum care after a pregnancy with gestational diabetes
- Group Two - Standard postpartum care after a pregnancy with gestational diabetes plus on-line nutrition and physical activity education classes
- Group Three - Standard postpartum care after a pregnancy with gestational diabetes, on-line nutrition and physical activity education classes plus blood glucose testing

You will also be asked to complete a questionnaire about yourself (for example, your age, race/ethnicity, etc...).

6 Weeks Post-Partum
This routine visit as part of your normal care will occur 6-8 weeks after you have delivered your baby. This visit will take about 30 minutes.

At this visit we will discuss the results of your routine 2-hour glucose tolerance tests which is also part of our routine care.

6 Weeks to 3-Month Post-Partum
At 6 weeks to 3 month after you have delivered, all subjects will be asked to complete questionnaires about diet and physical activity levels. These questionnaires can be completed either through an on-line secure web-based system or by phone with a member of the study team. It will take about 30 minutes to complete these questionnaires.

Subjects in Groups 2 and 3 will also participate in a 1 ½ to 2 hour on-line nutrition and physical activity education class using Brainshark, a secure online meeting platform. Around the time of the class, you

Participant's Initials: _____

will be asked to submit one favorite family recipe on an index card, which will be modified by the nutritionist. In addition, you will be asked to self-report your weight as well.

Subjects in Group 3 will also need to test their blood glucose levels 4 times a day (before breakfast, 1-hour after breakfast, lunch and dinner) for 4 days in row once a month for 6 months. A blood glucose meter and test strips will be provided by the study. Subjects will need to report the results of their testing to the study team either by e-mail, fax, or mail.

6-Month Post-Partum
All subjects will be asked to complete questionnaires about self- and infant-care needs, breastfeeding, and depressive symptoms. These questionnaires can be completed either through an on-line secure web-based system or by phone with a member of the study team. It will take up to 30 minutes to complete these questionnaires.
Around the time of the class, you will be asked to submit one favorite family recipe on an index card, which will be modified by the nutritionist. In addition, you will be asked to self-report your weight as well.

9-Month Post-Partum
All subjects will be asked to complete questionnaires about diet and physical activity levels. These questionnaires can be completed either through an on-line secure web-based system or by phone with a member of the study team. It will take up to 30 minutes to complete these questionnaires.

Subjects in Groups 2 and 3 will also participate in a 1 ½-2 hour group on-line nutrition and physical education online class using Brainshark, a secure online meeting platform. You will be asked to self-report your weight at this time as well.
Subjects in Group 3 will stop testing their blood glucose levels after completion of the 9-month online education class.

12-Months Post-Partum
All subjects will be asked to complete questionnaires about your satisfaction with the health care system and your health-seeking behaviors. These questionnaires can be completed either through an on-line secure web-based system or by phone with a member of the study team. It will take up to 30 minutes to complete these questionnaires. You will also be asked to provide your current weight at this time as well.

In addition, if you have had another OGTT or fasting glucose test done you will be asked to sign a release so the study team can receive the results of this test along with your most recent weight measurement.

Additional Information
The information that you provide to us from your completed questionnaires will be combined with data from your medical records, including information on your pregnancy, laboratory test results, medical procedures, and your medical history.

Risks, Potential Risks and/or Discomforts

Participating in research studies often involves possible risks and/or discomforts.

For women assigned to Group 3, you may experience minor discomfort from the self testing of your blood glucose during the 4 times a day for 4 days in a row testing periods. This discomfort will be similar to that which occurred during your pregnancy, where you tested your blood glucose levels to better manage your gestational diabetes. If excessive bleeding or bruising occurs, please contact the

Participant's Initials: _____

Principal Investigator of the study, Florence Brown, M.D. at 617-309-2496 between 9a.m and 5p.m Monday through Friday. After 5p.m. Monday through Friday or on Saturday or Sunday, please contact 617-632-7243 pager number 31869.

Also, some questions from the questionnaires are sensitive and may raise personal issues. If you feel uncomfortable answering any questions, please feel free not to answer that question. Questionnaire responses will be reviewed upon return of the questionnaire. If responses require further attention, a member of our study staff will contact you by phone or mail within 48 hours of the questionnaire return to make arrangements for you to speak with a doctor or other medical care provider to further address the issue.

If at any time you feel uncomfortable participating in any portion of the study, you need not participate. Finally, personal identifying information you provide us will be kept confidential and will be stored in a password-protected database in the locked office of Dr. Florence Brown.

Your responses from questionnaire data, as well as medical information will be stored separately from information that can identify you in order to ensure your confidentiality. Only approved study staff will access to this non-identifying information, which will be stored in a password-protected database. We do not anticipate any breeches of confidentiality; however, if a breech occurs, we will contact you immediately regarding any information that may have been compromised.

If you are assigned to either Group 2 or Group 3, you will be asked to attend 2 on-line nutrition and physical activity classes. To ensure the security of data and information, the classes will take place online via a highly secure web platform.
In addition to the possible risks and/or discomforts listed above, there may be risks/discomforts involved in this study that are not known at this time.

New Information and Questions

If any new information about the study becomes known that could affect you or might change your decision to participate in this research study, you will be contacted by the study investigator.

If you have any questions at any time about this study, you may contact the study investigator Florence Brown, M.D. at 617-309-2496.

Alternative Procedures/Treatments

You do not have to participate in this study to receive medical care for your past history of gestational diabetes. You will receive standard care whether or not you participate.

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Information for Women of Childbearing Potential

If you become pregnant during the course of the study, please notify Florence Brown, M.D. by calling 617-309-2496. While participation in the study will not affect your current pregnancy, you may no longer be eligible to participate in the study. Determination of your eligibility will be made by Florence Brown, M.D and will be communicated to you through a mailed letter within 1 week of our having received notification of a new pregnancy.

Removal from Study

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

- You do not complete the 6-week postpartum 75 gram 2-hour oral glucose tolerance test
- You do not complete the screening questionnaire
- You do not complete at least 3 of the 4 study questionnaires
- You do not participate in the on-line nutrition classes (Groups 2 and 3 only)
- You do not test your blood glucose levels at least 75% of the time 4 times a day for 4 days a month (Group 3 only)
- If you choose to take a 75 gram 2-hour OGTT at 12-months after your baby is delivered and you do not give permission for the release of your 75 gram 2-hour oral glucose tolerance test at 1-year after the delivery of your baby
- Change in your medical condition, including a diagnosis of diabetes or the occurrence of a new pregnancy.
- Discontinuation of the study for any reason by the sponsor, investigator, Joslin Diabetes Center, or government agencies.
- Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by research participants in this study.

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

Adverse Events or Injuries

If as a direct result to your participation in this study, you experience adverse event or study related injury, you should immediately contact the study investigator Florence Brown, M.D. at 617-309-2496 between 9a.m. and 5p.m. Monday through Friday. After 5p.m. Monday through Friday or on Saturday or Sunday, please contact: 617-632-7243 pager number 31863. You will be contacted by a member of the study staff within 1 hour. If it is a medical emergency, please call 911 and then contact our study staff as soon as possible at the numbers provided above.

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

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

Participant's Initials: _____

Anticipated Benefits

There is no guarantee that you will benefit by participating in this study. You might benefit from this study by making healthier choices after having gestational diabetes and preventing diabetes in the future. Additionally other might benefit from the information we learn from this study.

Remuneration/Reimbursement

If you complete the study you will receive $50.00. If you do not complete the study, this amount will be pro-rated based on what study procedures you have completed prior to your withdrawal from the study. Payment will be made to you by check.

If this study should result in the development of any marketable product, it is not the policy of the Joslin Diabetes Center to share any profits with participants in the research study.

Responsibility for Costs

All on-line classes for the study will be done at no cost to you.

You or your insurance company may be responsible for the costs of the routine care tests such as the 6 week and 1-year 75 gram 2-hour OGTT which would be done whether or not you participate in the study, as these tests are a part of standard care.

Right to Withhold or Withdraw Consent, or Refuse Procedures

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

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

If you withdraw your consent or refuse a procedure, you will not be allowed to continue your participation in this research study. To formally withdraw your consent to participate in this research study, you must provide a written and dated notice of this withdrawal to the study's investigator Florence Brown, M.D. Please mail your letter of withdrawal to: Florence Brown, M.D., Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

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

Privacy & Confidentiality – HIPAA Authorization

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

This section gives more specific information about the privacy and confidentiality of your medical information. It explains what medical information will be collected during this research study and who

Participant's Initials: _____

may use, disclose or receive your medical information. It also describes how you can revoke this authorization after you sign this document and your right to inspect your medical information.

We will only collect medical information that is needed for this research study. Your medical information will only be used and/or disclosed as explained in this document or as permitted by law.

The results of this research study may be published in scientific journals and/or presented at medical meetings. If the results of this study are published and/or presented, your identity will be kept confidential.

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

Medical Information Involved in this Study

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

- Height
- Weight immediately before pregnancy
- Weight prior to delivery
- Your age at delivery
- Gestational age at delivery
- Race/ethnicity
- Use of insulin in pregnancy
- Contraceptive use/type (past or current?)
- Gravidity and parity
- Breastfeeding exclusively (yes or no)
- Bottle-feeding exclusively (yes or no)
- Mixed breast and formula – how many bottles of formula/day
- Breast feeding exclusively duration
- Mixed breast and bottle duration
- Your weight at 3, 9, and 12 months after the delivery of your baby
- 6 week glucose tolerance test results
- 1 year 75 gram 2-hour oral glucose tolerance or fasting glucose test results
- Blood glucose meter values

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

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

- Your answers to study questionnaires
- Your blood glucose levels (if you are assigned to Group 3)
- Your weight at 3, 9, and 12 months after the delivery of your baby
- 6 week oral glucose tolerance test results
- If you choose to take this, results from your 1 year oral glucose tolerance test

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

Participant's Initials: _____

Access to Medical Information Involved in this Study

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

- Authorized representatives of the Joslin Diabetes Center Audit and Compliance Office;
- Authorized representatives of the Joslin Diabetes Center Committee on Human Studies;
- Other medical centers/institutions/study investigators outside the Joslin Diabetes Center participating in this research study;
- Governmental entities that have the right to see and/or review research and/or your medical information, such as the Office of Human Research Protections and the Food and Drug Administration;
- Hospital and other accrediting agencies;
- Clinical staff not involved in this study who may become involved in your care, if the medical information is potentially relevant to treatment;
- Your health care insurer or payer, if necessary, in order to secure their payment for any covered treatment not paid for by this study;

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

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

Right to Withhold or Withdraw Authorization

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

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

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

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

Participant's Initials: _____

VOLUNTARY CONSENT & AUTHORIZATION

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

I have been informed of and understand the purpose of the research study entitled the, "Postpartum Gestational Diabetes Follow-up Study" and the study's procedures. I have been informed of and understand the foreseeable risks, potential risks, discomforts, and benefits associated with this study. I have been advised of and understand that unforeseen complications may occur. I understand that I may or may not be entitled to free medical care or compensation in the event that I am injured as a result of my participation in this study. I understand that if this research study should result in the development of any marketable product, it is not expected that any profits would be shared with me.

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

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

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

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

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

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

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

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

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

_____ _____
Signature of Participant or Participant's Representative *Date*

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

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

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

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VERIFICATION OF EXPLANATION

I hereby certify that I have explained to the above-named participant the purpose of the study entitled the, "Postpartum Gestational Diabetes Follow-up Study", the nature of the study procedures, and such foreseeable risks, potential risks, discomforts, and benefits that may result from their participation in this study. This explanation was made in appropriate language. I have advised the above-named participant to contact their primary care doctor regarding his/her participation in this study, if such contact has not been previously made. I have asked the above-named participant if they have any questions and/or concerns regarding this research study or any of the study's procedures, and I have answered his/her questions to the best of my ability.

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

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

_____ _____

Signature of Investigator or Investigator's Representative *Date*

_____

Investigator or Investigator's Representative (Print Name)

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