Joslin Diabetes Center

Committee on Human Studies

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

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

Funding: Roche Diagnostics

Study Contact: Florence M Brown 617-309-2496

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1. PURPOSE OF PROTOCOL:

To conduct an intervention study to improve adherence rates to post partum screening and attainment of weight loss targets in women with gestational diabetes through a pilot randomized controlled trial, involving the following three groups:

Group 1: (**see Table 1**) Standard care—Per usual care patients will receive a letter reminding them to schedule a 75 gram 2 hour Oral Glucose Tolerance Test (OGTT) 6 weeks post partum and see their Joslin provider to discuss the results. At 12 months +/- 3 months, we will ask women if they received a 75 gram 2 hour OGTT or had a fasting glucose lab test. For those women who have received this test, we will request the results as well as a documented weight from the study participant via self-report or from the participant's health care provider. In addition, participants will be asked to complete a questionnaire at 6 weeks to 3 months, 6, 9, and 12 months postpartum.

Group 2: (**see Table 2**) On-line nutrition and physical activity class—In addition to standard care described above, study subjects will participate in 1.5 to 2 hours nutrition and physical activity online class at 6 weeks to 3 months and 9 months. The online classes will be hosted via a highly secure online platform- Brainshark. Women will also be asked to self-report their weight at these times. At 12

months +/- 3 months, we will ask those women who chose to receive diabetes screening (either a 75 gram 2 hour

OGTT or a fasting glucose lab test) to provide the results of either of these tests, as well as a documented weight. The weight can either be self-reported or from their health care provider at 12 months (+/- 3 months postpartum). Participants will also be asked to complete a questionnaire at 6 weeks to 3 months, and 6, 9, and 12 months postpartum.

Group 3: (**see Table 3**) On-line nutrition and physical activity class and block blood glucose testing—This group will take part in the above-mentioned standard care and on-line nutrition and physical activity classes at 6 weeks to 3 and 9 months. In addition, participants in this group will take blood glucose levels with provided meters and test strips four times a day for 4 consecutive days once a month starting at 3 months postpartum and concluding at 9 months postpartum to check patterns of glucose before breakfast and 2 hours after each meal. Women will also be asked to self-report their weight at these times. For those women who choose to have diabetes screening at 12 months +/- 3 months through either a 75 gram 2 hour OGTT or a fasting glucose taken at a laboratory, we will request the test results at that time point. We will also collect the study participants weight from either self-report or their health care provider at 12 months postpartum. Each participant will be asked to complete a questionnaire at 6 weeks to 3months, and 6, 9, and 12 months postpartum.

OUTCOMES:

1. Adherence to diabetes screening using the 75 gram 2 hour OGTT or fasting blood glucose at 12 months (+/- 3 months)
2. Lab results from the fasting glucose test or results from a 75 gram 2 hour OGTT at 12 months among women who choose to take the diabetes screening test.
3. Postpartum weight loss (target 7% less than the pre-pregnancy weight for overweight/obese women and back to pre-pregnancy weight for normal BMI women). This will be based on medical record information on pre-pregnancy weight and self-reported or health-care provider reported weight at 12 months.
4. Determine to what extent barriers to health impact adherence rates to post partum screening and weight loss targets through a web-based questionnaire collected on the 6 weeks to 3 months, 6, 9, and 12 month questionnaires. These questionnaires will assess whether: lack of self care, perception of high infant care giving needs, fear of diabetes diagnosis and postpartum depressive symptoms, difficulty accessing medical care, dissatisfaction with medical care or primary care physician not recommending screening are associated with poorer adherence to diabetes screening guidelines and weight loss goals.

Study aims are:

1. Determine the extent to which women who receive a postpartum group nutrition intervention and/or block blood glucose testing return for a 12 month (+/- 3 months) follow-up screening for diabetes with either a fasting blood glucose test or a 75 gram 2 hour OGTT compared to women who receive standard care. *We hypothesize that women in Group 3 will be the most likely to return for screening at their 12 month follow-up (+/-3 months).*
2. Determine the extent to which women who choose to have diabetes screening conducted at 12 months postpartum and who receive a postpartum group nutrition counseling intervention and/or block blood glucose testing are more likely to have fasting glucose or a 75 gram 2 hour OGTT results within normal range at 12 months (+/- 3months) compared to women who receive standard care.
3. Determine the extent to which women who receive a postpartum on-line nutrition and physical activity counseling intervention and/or block blood glucose testing will meet postpartum weight goals at 12 months postpartum (i.e. more likely to lose 7% of their pre-pregnancy body weight if

they have a BMI >=25 or return to their pre-pregnancy weight if their BMI<25) compared to women who receive standard care.

2 STUDY DESIGN:

METHODS:

Study Population: During the 3rd trimester of pregnancy and up until 3 months postpartum, we will recruit a total of n=30 women (10 women in each group) with GDM or a recent history of GDM, who are seen by clinical staff at the Joslin Diabetes Center/Beth Israel Deaconess Medical Center's (JDC/BIDMC) Diabetes and Pregnancy Program. Study participants would have delivered between June 1, 2012 and May 31, 2016. Recruitment for the study will occur at Joslin Diabetes Center after the second visit for GDM in the Diabetes and Pregnancy Program. A research assistant will provide information about the study, review an informed consent form and offer participation in the study. Potential subjects will be advised that participation is voluntary and should they agree to participate in the study, they will be randomized to 1 of three intervention groups to which they will not have a choice of group assignment.

Proposed Study Design: This is a pilot study, where we propose to conduct a 3-grouped randomized controlled trial to evaluate whether a 1 ½ to 2 hour on-line nutrition and physical activity intervention +/- block testing of blood glucoses fasting and 2 hours after each meal for 4 days/month from starting at 3 months postpartum and concluding at 9 months postpartum will 1) improve adherence to the receipt of diabetes screening at 12 months postpartum through the recommended 75 gram 2 hour glucose tolerance test or fasting blood glucose test, 2) lower glucose values on the 75 gram 2 hour oral glucose tolerance test or fasting blood glucose test and 3) improve attainment of weight loss targets among women with a recent history of GDM. Patients will participate in an online nutrition and physical activity class at 6 weeks to 3 months and 9 months for women assigned to both groups 2 and 3. For those women assigned to group 3, they will also do block testing using an assigned blood glucose meter and test strips 4 times a day for 4 consecutive days each month, starting at 3 months and ending at 9 months. Women will have the option of submitting meter BG data via e-mailed logs or downloading directly to the clinic using Diasend software. More information about this will be discussed below. Once downloaded, the Diasend software creates a PDF document with all recorded blood glucose values. For purposes of this study, we will obtain a Diasend account specific to this study, which will allow women to download blood glucose information with an anonymous unique identifier that can be accessed by the study's Principal Investigator and CITI-certified, IRB-approved research assistant. Upon accessing the PDF document with the blood glucose meter information, both the PI and the Research Assistant can link blood glucose data with questionnaire and other health information collected in this study through the unique identifiers. More information about the security of the account and linking of data is provided below in Section 6.

On-line Nutrition and Physical Activity Counseling:

The nutrition and physical activity topics for groups 2 and 3, which will be taught using a web-based platform will include the following information by nutrition visit. Diet and exercise interventions will be flexible and sensitive to cultural differences.

6 weeks to 3-month on-line class:

1. Healthy Plate and Portions: Review portion sizes using handouts. There will also be a focus on adding fruits and vegetables, learning about healthy versus unhealthy fat.
2. Review Weight Loss Goals: Subjects will weigh in privately at each visit. They will also generally discuss the benefit of weight loss on the reduction of risk of future type 2 diabetes in women who have had GDM.

3. Exercise Basics: Review options for moderate intensity cardiovascular exercise and strength training, including walking and the use of resistance bands, and discuss exercise goals. Links to exercise videos and resistance bands and door anchors will be provided.
4. Making Your Recipes Healthy: Focus on adapting popular recipes to make them healthy. Participants will be asked to submit one favorite family recipe which will be modified by the nutritionist. Around the time of each class, we will ask participants to mail a favorite recipe on an index card.
5. Breastfeeding and Feeding Your Infant/Toddler: Review/discuss the benefits of breastfeeding to mom and the baby including reducing maternal weight retention, and reducing infant and child obesity. Review optimal timing of introduction of solid foods and types of foods healthy for your child.
6. One on one follow phone call by the nutritionist to the participant after the class to discuss questions about the material presented in the class and modifications to the favorite recipe.

9 month on-line class:

1. Healthy Plate and Portions: Review portion sizes using handouts. We will re-emphasize the importance of adding fruits and vegetables, and discuss healthy and unhealthy fats based on current dietary habits.
2. Review Weight Loss Goals: Subjects will weigh in at this time point and discuss the benefits of weight loss on the reduction of risk of future type 2 diabetes in the mom.
3. Breastfeeding and Feeding Your Infant/Toddler: Review/discuss the benefits of breastfeeding to mom and the baby including reducing maternal weight retention, and reducing infant and child obesity. Discuss healthy foods older infants/young toddlers should eat that could reduce the risk of childhood obesity.
4. Exercise- Review of exercise benefits previously discussed in the first class.
5. Supermarket Smarts: Tips for making healthy choices at the grocery store.
6. Dining Out: Review how to make healthier choices when dining out, with instruction including a sample restaurant menu.

Block Blood Glucose Monitoring:

The blood glucose monitoring intervention- block testing of morning fasting and 2-hour post breakfast, lunch and dinner blood glucoses will be performed for 4 consecutive days every month, starting at 3 months and ending at 9 months. The study staff will review downloaded data with 1-week of the study participant downloading her meter information into Diasend or submitting via e-mail. Upon review, in the event of a high (fasting $\geq$ 126 mg/d; postprandial $\geq$ 200 mg/dl), we will notify the study participant of the need to conduct a laboratory glucose at the Joslin Diabetes Center and of the possibility of additional testing as necessary to ensure that the participant has not developed type 2 diabetes. If this occurs, the study participant will be contacted by our study's CITI-certified IRB-approved research assistant to schedule a laboratory appointment for this additional testing. This is to ensure that the participant does not go without treatment of type 2 diabetes, should they develop it.

Blood glucose meters and test strips will be provided to patients and meter data will be uploaded to the Diasend website using the unique identifiers. This unique identifier will be used by study participants to login to the Diasend website and will serve as a username. Each participant will also select their own password. The IRB-approved, CITI-certified Research Assistant will then print out the information from either the Diasend platform of the e-mailed logs and enter the data into a secured database and link it to the questionnaire and health information data collected in the study. This link will not include linking

any blood glucose data from the blood glucose meters to personal identifiers.

The Diasend software is currently used by Joslin Diabetes Center and Joslin patients for clinical purposes and is secure. We will set up a unique account with Diasend to allow for our IRB-approved, CITI-certified Research Study Staff to provide a unique identifier to each woman in the study. This unique identifier will be used by study participants to login to the Diasend website and will serve as a username. Each participant will also select their own password. The glucose monitor will be downloaded upon successfully logging in using the unique identifier and password. The information downloaded will not be traceable, as only the PI of the study will have access to the link between the study participant and the unique identifier. Detail on protection of data and confidentiality is described below in Section 6.

Participants in this group of the study will be notified of the dates for blood glucose testing at the beginning of the study. Participants will receive a reminder postcard by mail or e-mail about testing of blood glucose levels 1 week before testing is to begin. If participants have not returned their blood glucose data within 5 days of the pre-scheduled dates, a reminder letter will be mailed. If blood glucose data is not received by 10 days, the Research Assistant will contact the study participant by phone to remind them to please return the blood glucose data.

Questionnaire to Assess Barriers to Follow-up:

A short screening questionnaire will be used to determine whether a woman is eligible to participate in our research study, based on the eligibility criteria described below in Section 3. The screening questionnaire will also ask general non-identifiable questions about the respondent's age (not date of birth), race/ethnicity, highest level of educational attainment, and income level. No identifying or personal information will be collected on the screening questionnaire. These questions will only be used to report response rates, essential for determining whether women who are eligible and agree to be randomized for the intervention study differ from those who do not agree to randomization or participation in the intervention. The IRB-approved CITI-certified Research Assistant will administer the screening questionnaire. Details on recruitment and consenting are described below in Sections 7 and 8.

The purpose of the 6 weeks to 3 months, and 6, 9, and 12 month web-based questionnaires is to determine the association between barriers to care and postpartum diabetes screening in women with a history of GDM. Specifically, we will evaluate self-care and efficacy, perception of infant care giving needs, fear of diabetes diagnosis, depressive symptoms, as well as access to and satisfaction with medical care. We will also ask women whether or not a physician referred them for diabetes screening. We will also assess women's adherence by asking whether they received diabetes screening (either a fasting glucose or a 2-hour 75 gram oral glucose tolerance test) at 12 months. In addition to collecting this information, we will ask women about their marital status, parity, medical history, breastfeeding behaviors, as well as information on diet (using a validated food frequency questionnaire), and physical activity levels. We will also obtain information on partner and family support. The web-based questionnaire will be on a secure server using Red Cap software available through Harvard Medical School. We will also ask women to report their current weight for each questionnaire. Data on their most recent pregnancy is also available, including total weight gain and blood glucose control during pregnancy.

Laboratory Data:

For women reporting having received diabetes screening, we will ask for authorization to collect the laboratory results from the screening test. The study participant will be mailed an IRB-approved medical authorization and release form requesting data on their postpartum fasting glucose or 2-hour 75 gram

oral glucose tolerance test, and most recent postpartum weight, as documented by their primary care physician. Once the medical authorization and release form have been signed and returned to our study team, we will collect information from the ordering physician on either a fasting glucose or a 75 gram 2-hour OGTT, per the study participant's authorized consent, as well as the recent postpartum weight.

Table 1 – Group 1 Standard Care

Contact 1 (Enrollment/ Randomization)	Contact 2 (6 weeks post-partum)	Contact 3 (6 weeks to 3 months post-partum	Contact 4 (6 months post-partum	Contact 5 (9 months post-partum)	Contact 6 (12 months post-partum)
Informed Consent	75 gram 2-hour OGTT (at Joslin or through OB)	Completion of Study questionnaires	Completion of Study questionnaires	Completion of Study questionnaires	Completion of Study questionnaires
Determination of Eligibility	Visit to Joslin provider				Results of 75 gram 2-hour OGTT or glucose (if done) Obtain weight
Randomization					

Table 2 - Group 2 Standard Care with Group Nutrition Visits

Contact 1 (Enrollment/ Randomization)	Contact 2 (6 weeks post-partum)	Contact 3 (6 weeks to 3 months post-partum	Contact 4 (6 months post-partum	Contact 5 (9 months post-partum)	Contact 6 (12 months post-partum)
Informed Consent	75 gram 2-hour OGTT (at Joslin or through OB)	Completion of Study questionnaires	Completion of Study questionnaires	Completion of Study questionnaires	Completion of Study questionnaires
Determination of Eligibility	Visit to Joslin provider	Participate in Nutrition and physical activity Class online Record weight		Participate in Nutrition and physical activity Class online Record weight	Results of 75 gram 2-hour OGTT or glucose (if done) Obtain weight
Randomization					

Table 3 - Group 3 Standard Care with Nutrition Group Visits and block Blood Glucose Checking

Visit 1 (Enrollment/ Randomization)	Visit 2 (6 weeks post-partum)	Visit 3 (6 weeks to 3 months post-partum	Visit 4 (6 months post-partum	Visit 5 (9 months post-partum)	Visit 6 (12 months post-partum)
Informed Consent	75 gram 2-hour OGTT (at Joslin or through OB)	Completion of Study questionnaires	Completion of Study questionnaires	Completion of Study questionnaires	Completion of Study questionnaires
Determination of Eligibility	Visit to Joslin provider	Participate inNutrition and physical activity Class online		Participate inNutrition and physical activity Class	Results of 75 gram 2-hour OGTT or glucose (if done)

		Record weight		online Record weight	Obtainweight
		Monthly BG checking with BG meter, 4 times a day for 4 consecutive days	Monthly BG checking with BG meter, 4 times a day for 4 consecutive days	Monthly BG checking with BG meter, 4 times a day for 4 consecutive days	
Randomization					

3. INCLUSION / EXCLUSION CRITERIA

Inclusion criteria:
1. Gestational Diabetes
2. Age between 21 and 45 years
3. Preconception BMI 19-40
4. Seen for at least 2 visits in the Diabetes in Pregnancy Program during their pregnancy
5. Singleton pregnancy

Exclusion criteria
1. Preexisting diabetes or diabetes diagnosed at the 6 week 75 gram 2 hour OGTT
2. BMI >40
3. Multiple gestation (i.e. twins, triplets, etc.)

4. DATA ANALYSIS / SUBJECT SELECTION

For aim 1, we will calculate the proportion of women who received postpartum diabetes screening in each group using intention-to-treat analysis. We will calculate the association between the interventions versus standard care by calculating chi-square and p-values to assess statistical significance. For aim 2, we will evaluate the association between our intervention and continuous blood glucose levels among women who received the 12-month 75 gram 2 hour OGTT or glucose. We will use ANOVA to calculate F-statistics and p-values to determine whether the intervention was associated with improved blood glucose levels compared to the standard care. Similarly, for aim 3, we will evaluate the association between our intervention and continuous weight measurements using ANOVA. As a secondary hypothesis, we will use multivariable binomial regression to evaluate the association between age, race/ethnicity, sociodemographic factors, self-care, perceived infant care giving needs, fear of diabetes, and access/satisfaction with medical care, and adherence to postpartum diabetes screening at 12 months. We will calculate risk ratios and 95% confidence intervals, adjusting for potential confounders, including sociodemographic factors. We will primarily assess these results for directionality. We will use SAS version 9.2 (Cary, NC) for all analyses.

The proposed project is a pilot study. Therefore, we anticipate having limited power to detect statistically significant results. However, the direction and magnitude of the associations will provide necessary data required for a larger research study to further improve adherence to diabetes screening guidelines after GDM, as well as potentially improve blood glucose results for women in the first year postpartum and reduce weight retention. As such, this study is clinically significant, given that it may provide insight into how to improve adherence to follow-up diabetes screening and subsequent prevention or delayed diabetes diagnosis. This data analysis will be performed by Dr. James-Todd and Soh.

Local Interim Data Analysis/Data Monitoring Plan

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CHS#2012-16

We will conduct interim data analysis during recruitment, every 3 months during the study, as well as at the conclusion of the study. During recruitment, we will generate response rates. During the study, we will do interim data analysis following the 6 weeks to 3 months and 9 month nutrition and physical activity on-line class to ensure evaluation of the adherence of study participants to the intervention. In addition, we will do spot checks of data for the 6 weeks to 3 months and 9 month questionnaires, checking records of 10% of data housed in the password-protected database for data quality and accuracy within 1 month of completion. These checks will be conducted by the Principal Investigator and will be comparing written reports and medical record data entered by the CITI-certified, IRB-approved Research Assistant based on available data at the time of each check. Means, ranges, and standard deviations will also be calculated to determine whether any data points are severely out of range. If inaccuracies are found, then study staff will meet, discuss data collection processes, identify reasons for inaccuracies, and improve data entry and management systems. In addition, a data check will be conducted approximately 1 month after the identification of any inaccuracies to ensure that any issues involving the data entry and management systems have been resolved.

While similar steps will be taken to evaluate the data quality and accuracy of the 6-month questionnaire, due to the more sensitive nature of questions contained in the 6 month questionnaire (i.e. depressive symptoms), we will evaluate the 6 month questionnaire in real-time. Each 6 month questionnaire will be reviewed by the PI or CITI-certified Research Assistant within 24 hours of online submission or telephone interview. If a study participant answers "Most of the time" or "Some of the time" to the question asking, "The thought of hurting myself has occurred to me," we will notify the PI and have the IRB-approved, CITI-certified study staff mental health provider contact the study subject via phone to ensure the subject's health and safety. Study participants will be made aware of this procedure per the informed consent.

In addition to data management, adverse event reporting will also be recorded and managed by study staff. While we do not anticipate any adverse events, we will ensure all study participants are aware of potential benefits and risk of participating in the study. If at any time study participants feel that their participation in the study has resulted in injury (for purposes of this study, it could include bruising from finger sticks), we will advise them to contact our CITI-certified, IRB-approved to directly contact the Principal Investigator of the study. We will immediately report any adverse events to the Joslin IRB. If deemed severe enough, we will halt the study.

5. POSSIBLE BENEFITS:

Individuals in groups 2 and 3 may benefit from learning about healthy nutrition, exercise and weight loss targets to prevent type 2 diabetes in the mother and reduce overweight and obesity in the offspring. Individuals in group 3 may also benefit from finger stick glucose monitoring to assess the effect of various types of food on glycemia, which may provide direct feedback about food choices. On the other hand, individuals in group 1 may benefit from better weight management due to reporting on their weight measurements throughout the study time period. Society may benefit from learning whether a simple lifestyle intervention of diet and exercise education +/- periodic blood glucose monitoring results in increased adherence to recommended 12 month (+/- 3 months) follow-up of screening for diabetes with 75 gram 2 hour OGTT or glucose, as well as improve blood glucose results compared to women who receive standard care. In addition, society may benefit from learning whether a nutrition intervention during the immediate postpartum could aid in women losing 7% of their pre-pregnancy body weight if they have a BMI >=25 and return to their pre-pregnancy weight if their BMI<25 compared to women who receive standard care. If found to be effective, this intervention may provide insight into how to improve adherence to follow-up diabetes screening and subsequently prevent or delay diabetes diagnosis in a high risk group of women who have had a recent GDM-complicated pregnancy.

6.POSSIBLE RISKS:

Risks from learning and following a healthy lifestyle are minimal except that fruits and vegetables may be more expensive than high energy food with low nutritional value and may take a longer time to prepare. Risks from finger stick monitoring may include pain and bruising at the site of the finger prick. However, most of these patients (or can we say all) have previously received blood glucose monitoring training and have regularly tested their blood glucose levels during their GDM-complicated pregnancy. As such, risks may be minimal, as these women have been trained in the appropriate way in which to tests their blood glucose levels with minimal pain.

In addition to finger stick-related pain, women participating in this study will be asked to answer sensitive questions regarding depressive symptoms and self-care. We will make women aware that responding to any questions or participating in this study is completely voluntary by stating this in the informed consent and on study questionnaires. If women are uncomfortable answering any one or a number of questions, we will also make them aware that this will not alter their ability to participate in the remainder of the study.

Due to the sensitive nature of certain questions and the collection of medical record data, breach of confidentiality is also a potential risk for participation in this study. However, we will take all necessary precautions, described below, to minimize this and all other risks mentioned.

Protection against Risks: The principal and co-investigators are taking important safety measures to reduce participants' risk. First, the dataset containing PHI will be stored separately from all questionnaire and medical record data collected in this study. A unique identifier will be created for each study participant. Only the principal investigator, one Joslin-based co-investigator (Jo-Anne Rizzotto), and the Research Assistant will have access to the password-protected dataset containing personal identifiers and the unique identifiers. This data set will be housed on a single encrypted computer located in a locked office at Joslin Diabetes Center. In order to create the separate dataset that will be used for analysis, the Principal Investigator will link the questionnaire and health-related information datasets using a unique identifier (i.e. Study ID). This dataset will not contain any PHI. Second, the dataset used for analysis will be password protected and encrypted. IRB-approved co-investigators of this study will have access to this dataset for analysis purposes only. Co-investigators will have to save a copy of the analysis-only dataset (i.e. the dataset not containing PHI) on an encrypted, password-protected computer. The dataset will also be password protected. For those co-investigators outside of Joslin Diabetes Center, the password-protected, encrypted analysis dataset will be transferred to their computers via a Dropbox shared folder. Once they have downloaded and saved the dataset on their encrypted, password protected computer, they will delete the dataset from study staff shared Dropbox folder.

The combination of password protected dataset, encrypted and password-protected computer, and locked office, along with storing the PHI containing dataset unlinked from questionnaire and health-related data collected within the study on a single computer, with restricted access will minimize this potential risk of breach of confidentiality.

Additional safeguards are being taken for the use of a web-based questionnaire for data collection. For this, we propose to use REDCap, a free, secure, HIPAA compliant web-based application hosted Joslin Diabetes Center. In collaboration with a consortium of academic and non-profit institutional partners, Vanderbilt University developed this software tool and workflow methodology for electronic collection and management of research and clinical data. A study-specific data dictionary is defined by members

of the research team with assistance from Harvard Catalyst | The Harvard Clinical and Translational Science Center EDC Support Staff. This iterative development and testing process will allow for a well-planned data collection strategy. Using REDCap, our research team will be able to design a web-based survey and engage potential respondents with a variety of notification methods. REDCap has flexible features and provides an intuitive interface to enter data with real time validation (automated data type and range checks). Easy data manipulation with audit trails, reports for monitoring and querying participant records, and automated export mechanism to statistical packages, such as SAS are also included. We will conduct a pretest of the web-based questionnaire among our research team prior to posting it live. The web-based questionnaire will be by invitation only and will require a special code (the login will be the unique identifier assigned to each study participant and password provided by our study staff) in order for study participants to complete the questionnaire. This will also ensure that only one questionnaire will be completed by a given participant per each study time point. By using REDCap, no personal identifiers, including IP addresses will be stored.

For those participants in groups 2 and 3, we will ensure confidentiality within the group nutrition classes, by obtaining verbal consent from study participants regarding maintaining the confidentiliaty of any information shared or learned during class. Currently, Joslin Diabetes Center conducts group nutrition classes during pregnancy. Similar to these classes, we will show a slide describing the requirement for confidentiality while taking the class. Once this slide is presented, the lead nutritionist, Jo-Anne Rizzotto will obtain verbal consent from all participants in attendance. This will occur prior to the start of both the 6 weeks to 3 months and 9 month postpartum online classes.

We will take special precautions for participants in group 3 to ensure that blood glucose data downloaded into the Diasend program is protected. We will set up an account with Diasend that will provide the study with the ability for only our study participants to access. Each participant will be provided with a specific log-in (separate from the unique identifier used in the rest of the study) and password. They will enter this into the Diasend program and then download their pump. The key to the unique identifier and specific log-in for this portion of the study will be stored on the Principal Investigator's encrypted, password protected computer. The key itself will also be password protected. This additional security step will provide increased protection for data collection. Data will not be able to be linked or traced to the specific study participant and linkage will require two steps to reduce potential risks associated with breach of confidentiality.

7. CONSENT PROCEDURES:

All interested women will be consented by a CITI-certified, IRB-approved research assistant who will meet with the woman following her appointment with her Joslin provider or be contacted by telephone to briefly discuss whether she is eligible. Eligibility will be determined through the brief screening questionnaire. If the woman is eligible for participation, she will be asked to read the consent form. The woman can either review the consent form at this time or take the consent form home for further review. If she would like to review and sign the consent form at this time, she will be enrolled into the study. If the woman chooses to take the consent form home for further review, she will be asked to return the consent form before or at her next Joslin appointment. Those women contacted by telephone will receive the consent form via US mail or email and will be asked to return it in a self-addressed envelope provided by the study or asked to fax back to # 617-309-2574. In either case, women will be told that if they have any questions regarding the study or consent form, to please contact the Research Assistant or Principal Investigator of the study at the phone number provided on the consent form. Upon receipt of the consent form, a duplicate copy of the signed consent form will be given to the subjects and women will be enrolled into the study.

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CHS#2012-16

8. RECRUITMENT / SOURCE OF SUBJECTS:

Women with gestational diabetes who have seen a Joslin Diabetes Center Diabetes and Pregnancy Program provider at least two times during their pregnancy between June 2012 and May 2016 will either be approached during a scheduled clinic visit or contacted by telephone by their provider (also co-investigator) or the Research Assistant. If interested in learning more about the study, the CITI-certified, IRB-approved Research Assistant will be introduced to the woman and will take the woman into a private room where the Research Assistant will describe the study in further detail. The Research Assistant will meet with the potential study candidate, inform the woman about the purpose of the study, as well as provide a brief description of the study design and outcome measures. Women will also be informed of possible benefits and risks of the study. At this time, the Research Assistant will obtain verbal consent to conduct the screening questionnaire to determine a woman's eligibility. If a woman is eligible, she will receive a study participant letter further describing the purpose of the study, as well as the informed consent form to which CITI-certified, IRB-approved Research Assistant will briefly review with the potential study participant. Each woman will be given time to review it before signing. During the review, if the eligible subject has any questions regarding the study, she can raise them with the CITI-certified, IRB-approved Research Assistant or the Principal Investigator. If the eligible subject wishes to bring the consent form home for review, she will be allowed to do so and will be asked to bring the form back on her next visit to Joslin for signing after further clarification of any queries. As mentioned above, the study participant will then receive a copy of the signed informed consent and will be enrolled into the study. At this time, we will use block randomization, using a random number generator to assign women into one of the three study groups. Block randomization will ensure an equal distribution of women into each arm. Women will not have the option of choosing their assignment. They will also not be blind to which group they have been assigned to for participation in the study.

9. RIGHTS AND PRIVACY:

The data for each subject will be extracted from her medical record data in Joslin Diabetes Center for statistical analysis by Dr. Michael Molla. After abstracting the data, it will be merged via the key with the personal identifiers dataset housed on Dr. Brown's computer (PI) with questionnaire data by Dr. Brown and the Research Assistant. Once this merge takes place, personal identifiers will be removed and only the unique study ID will remain attached to this information. As described in Section 6, the key to the code, linking the subject's personal information to the subject will be kept in a locked file in Joslin Diabetes Center. Only Dr. Brown (PI) and Jo-Anne Rizzotto RD will have access to the key to the code.

Only the following data from medical records will be sent to the co-investigators for data analysis:

- Height
- Weight immediately before pregnancy
- Weight prior to delivery
- Age at delivery
- Gestational age at delivery
- Race/ethnicity
- Marital status
- Education level
- Family income
- Use of insulin in pregnancy
- Contraceptive use/type
- Gravidity and parity
- Breast feeding 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
- Weight at 3 months and 9 months (groups 2 and 3) and 1 year +/- 3 months (all 3 groups)
- 6 week glucose tolerance test results
- 1 year glucose tolerance test results
- Barriers to adherence—healthy eating and physical activity (from questionnaire)
- Partner support
- self-care and –efficacy,
- perception of infant care giving needs,
- knowledge and fear of diabetes diagnosis,
- depressive symptoms (Edinburgh Postpartum Depressive Scale)
- satisfaction with medical care
- self-report of physician referral for postpartum diabetes screening
- History of other pregnancy complications

The co-investigators will not receive the PHI-containing dataset.

Please answer the following questions:

- Will medical history/clinical information be obtained from the subjects' medical records for the purpose of this study? If yes, please list what information will be recorded.

YES

- Height
- Weight immediately before pregnancy
- Weight prior to delivery
- Age at delivery
- Gestational age at delivery
- Race/ethnicity
- Use of insulin in pregnancy
- Contraceptive use/type
- Gravidity and parity
- Weight at 3 months and 9 months (groups 2 and 3) and 1 year +/- 3 months (all 3 groups)
- 6 week glucose tolerance test results
- 1 year glucose tolerance test results

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

  NO

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

  NO

10. OMIT PROCEDURES / LEAVE STUDY:

A subject who wishes to leave the study or not participate in any specific study procedures can inform CITI-certified, IRB-approved study staff at any time. Study participants will be given information, as to how to contact study staff or the Principal Investigator of the study. Written or verbal dissent will be accepted and a note will be included in the study participants file to ensure that all study staff are aware of participants' decision.

11. INCENTIVES / REMUNERATION:

Subjects in group 1 and 2 will receive $50 for completion of the study while subjects in group 3 will receive additional $50 for reporting their self- glucose tests done through 3 months- 9 months. If a participant only completes part of the study then the remuneration will be prorated. In addition, those who are randomized to the nutrition/exercise classes will receive reimbursement for parking.

12 months (Groups 1, and 2)	$50.00 check for completion of study
12 months (Group 3)	$100.00 check for completion of study

*** Identifiable Health Information**

Approved by
JDC/ CHS
CHS#2012-16

Data that includes any of the following identifiers are considered identifiable health information: ("X" denotes data to be collected)

- X Name
- X Social Security number
- X Medical Record Number
- X Address by Street Location
- X Address by Town/City/Zip Code
- X Date of Birth
- X Telephone Number
- X Electronic E-Mail Address

Approved by
JDC/ CHS
CHS#2012-16

CHS#: 2012-16
Date: 11/20/2015

Please answer the following questions:

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

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

Will your project involve research on living human fetuses?

- ☐ Yes
- X No

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

- ☐ Yes IND# or IDE# _____
- X No

Is review required by risk management foundation?

- ☐ Yes
- X No

_____ _____
Signature of Principal Investigator ***Date***

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

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

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

Approved by
JDC/ CHS
CHS#2012-16

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., Jacqueline Shahar, MEd, RCEP, C.D.E., Ashley Curran B.Sc., Celestine Warren, B.A.

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 31863.

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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COMMITTEE ON HUMAN STUDIES
Do Not Use After
MARCH 19, 2016

Participant's Initials: _____

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: _____

Additionally, whether or not you provide or withdraw your authorization will have no affect on your current or future relationship with a healthcare insurance provider.

Continuation of Authorization

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

Access to Medical Information

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

Participant's Initials: _____

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

VOLUNTARY CONSENT & AUTHORIZATION

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

I have been informed of and understand the purpose of the research study entitled 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**

APPROVED BY THE
JOSLIN DIABETES CENTER
COMMITTEE ON HUMAN STUDIES
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MARCH 19, 2016

Participant's Initials: _____

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

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

_____ _____

Signature of Participant or Participant's Representative *Date*

_____ _____

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

PLEASE NOTE

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

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

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COMMITTEE ON HUMAN STUDIES
Do Not Use After
MARCH 19, 2016

Participant's Initials: _____

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

VERIFICATION OF EXPLANATION

I hereby certify that I have explained to the above-named participant the purpose of the study entitled 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)

APPROVED BY THE
JOSLIN DIABETES CENTER
COMMITTEE ON HUMAN STUDIES
Do Not Use After
MARCH 19, 2016

Participant's Initials: _____