Informed Consent Form

TITLE: Minding the Gap: Improving Women's Health Through Coordinated Postpartum Planning

NCT NUMBER: NCT05430815

IRB APPROVAL DATE: September 21, 2023

You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. If you agree to be in the study, you will be one of 320 people who are being studied at Grady.

Why is this study being done?
This study is being done to test whether coordinated postpartum planning will improve women's health after pregnancy. You are being asked to be in this research study because you are currently pregnant and have either diabetes, high blood pressure, or pre-pregnancy obesity that started before this pregnancy or during this pregnancy.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your pregnancy or postpartum. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will be randomized to either receive the same usual care you would have otherwise received during your pregnancy or the same usual care plus postpartum planning visits with a trained healthcare professional at every prenatal care visit, a visit during your delivery admission to review your postpartum plan, and a check-in by phone or text in the first week after your baby is born. You will also be asked to complete a survey 12 weeks after you give birth and 14 months after, no matter which group you are randomized to.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Although this study is not designed to help you directly, being able to spend more time talking to a trained healthcare professional during and after your pregnancy may improve your ability to manage health conditions such as high blood pressure, diabetes, or pre-pregnancy obesity.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include some discomfort due to survey questions, and potential loss of privacy, or breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate and to continue to receive usual care at Grady.

Costs
You will not have to pay anything to be part of this study.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: Minding the gap: improving women's health through coordinated postpartum planning

Principal Investigator: Anne Dunlop, MD, MPH, Professor, Gynecology and Obstetrics

Study Supporter: National Institute of Minority Health and Health Disparities R01MD016031-01

Introduction
Thank you for your interest in our research study. We would like to tell you everything you need to think about before you decide whether or not to join the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. If you decide not to participate, you will continue to receive prenatal, delivery, and postpartum care at Grady.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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

What is the purpose of this study?
The purpose of this study is to test whether women who receive extra counseling about postpartum planning at prenatal care visits and phone calls following delivery have improved health following their pregnancy.

What will I be asked to do?
If you choose to participate in this study, you will be randomized to either receive the extra prenatal and postpartum counseling or the same prenatal care you would have otherwise. Randomization is like flipping a

coin to see which type of care you will get. This helps us have equal numbers of women in each arm with similar characteristics.

If you are randomized to receive usual care, you will attend prenatal visits throughout your pregnancy and schedule a postpartum visit between 4-12 weeks postpartum. You will also receive Grady initiated text reminders about your scheduled visit. We will ask you to fill out two surveys at 12 weeks after delivery and 14 months after delivery. The total duration of participation will be 18-20 months, depending on when you deliver your baby.

If you are randomized to the intervention, you will receive usual care (attend prenatal visits throughout your pregnancy and schedule a postpartum visit between 4-12 weeks postpartum). During each prenatal care visit between recruitment and delivery, you will complete a study visit with a study coordinator. Over the course of the visits, the coordinator will help you create a postpartum plan that is specific to your needs and provide you with educational materials and linkage to community resources as needed. Each visit will be about 30-45 minutes. The study coordinator will visit you during your delivery admission to review your postpartum plan, and will call you once after delivery (around 1 week after delivery) to check in with you. You will schedule your postpartum visit between 4-12 weeks after your baby is born and will receive reminders about the visit, as is usual care. We will ask you to fill out two surveys at 12 weeks after delivery and 14 months after delivery. The total duration of participation will be 18-20 months, depending on when you deliver your baby.

Who owns my study information and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if we use your de-identified information for further research. If you withdraw from the study, data that is already collected may still be used for this study.

What are the possible risks and discomforts?

There are potential risks related to the conduct of this study. A breach of confidentiality is unlikely but possible. In addition, it is possible that you may experience some distress during surveys, as the postpartum period can be stressful and about 12% of women experience either the 'baby blues' or postpartum depression. If you experience distress during the survey, you will be connected with resources, and you can either stop the survey or schedule another time to complete it.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about how to care for women postpartum. If you are assigned to the intervention, you may benefit from the additional opportunities to talk to a trained health professional about your health after delivering your baby. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get $25 for enrolling in the study, $25 after completing the 12 week survey, and $25 after completing the 14 month survey. If randomized to the intervention arm, you will receive $10 after each completed study visit. The number of study visits will depend on how far along you are in your pregnancy. You may have up to (8) eight study visits during your pregnancy, for a total of up to $155 if all visits are completed and (4) supplemental visits, if needed, which would increase the total compensation to up to $195. If you do not finish the study, we will compensate you for the visits and surveys you have completed. Intervention arm participants will receive a "Grady onesie" during the delivery admission visit.

What are my other options?

If you decide not to participate in this study, you will receive prenatal and postpartum care at Grady as usual with no change.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the National Institute of Health, the Emory Institutional Review Board, the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), will be shared with other researchers on request to help answer related scientific questions. In addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee the anonymity of your personal data. In order to access these data, a researcher at Emory or otherwise will have to agree not to try to identify you and commit to securing the data and destroying it following analysis.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you individual results from your survey responses or other data you provide.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:
The IIHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information. study. You may receive any non-research related treatment whether or not you sign this form.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use IIHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you will continue to receive prenatal care as usual.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institute of Health is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - The National Institute of Minority Health and Health Disparities is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

  - Government agencies that regulate the research including: Office for Human Research Protections.
  - Public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team by email (minding.the.gap.atlanta@gmail.com) or mail: Department of Gynecology and Obstetrics, 69 Jesse Hill Jr Drive, 4th Floor, Atlanta, GA 30303

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly, and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Dr. Anne Dunlop at [redacted] or [redacted]

- if you have any questions about this study or your part in it,
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**
If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**