CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: Effect of formal contraception handouts on postpartum birth control use and methods.

Principal Investigator: Christina DeAngelis, MD

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Telephone Number: Weekdays: 8:00am to 5:00 pm: 717-531-3503

Subject's Printed Name: _____

We are asking you to be in a research study.

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

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

KEY INFORMATION

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

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

We are asking you to take part in this voluntary research study because you are a healthy woman with a relatively low-risk pregnancy and are being seen here at either 35 Hope Drive, 121 Nyes Road or 3025 Market Street Camp Hill Obstetrics and Gynecology by Women's Health doctors.

What is the purpose of this research study?

The purpose of this voluntary research study is to find out if a handout on birth control options has an effect on birth control use 8 weeks after delivery. We are trying to improve ways of informing patients about their birth control options.

How long will the research study last?
Your participation in the study will begin when your pregnancy is 24-28 weeks along through 6 months after delivery.

What will I need to do?
You will be asked to fill out short questionnaires once during your pregnancy (at 24-28 weeks gestational age) and two more times after you deliver (8 weeks and 6 months after delivery).

What are the main risks of taking part in the study?
For this study, there is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

What are the possible benefits to me that may reasonably be expected from being in the research?
There are no benefits to you from taking part in this research. Results of the study may benefit other people in the future by determining the effect of educational handouts on birth control use after a woman delivers. A simple intervention like an educational handout may lead to better patient satisfaction and counseling efforts by healthcare providers.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

You may choose not to take part in this research study.

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

1. Why is this research study being done?
We are asking you to be in this research because you are a woman with a relatively low-risk pregnancy and are being seen here at either 35 Hope Drive, 121 Nyes Road or 3025 Market Street Camp Hill Obstetrics and Gynecology by Women's Health doctors.

This research is being done to find out if a handout on birth control options has an effect on birth control use 8 weeks after delivery. We are trying to improve ways of informing patients on their birth control options.

Approximately 224 people will take part in this research study here at either 35 Hope Drive, 121 Nyes Road or 3025 Market Street Camp Hill, Obstetrics and Gynecology.

2. What will happen in this research study?
If you agree to participate, you will first sign this consent form. You will receive a copy of the signed consent form for your records.

24 – 28 Week Prenatal Visit: At your 24-28-week prenatal visit, you will be asked to complete a short written research-specific questionnaire (this should take approximately 10-15 minute to complete), which you will hand back in once you have completed it. At your initial visit, you will be randomly assigned by a computer

program (i.e. "randomized") to receive either an informational handout on birth control or an informational handout on nutrition during pregnancy. You have a 50% chance of being placed in either group, similar to the odds of flipping a coin and landing on "heads" or "tails." The research team will not know which study treatment you are receiving, but the research team will be able to get this information quickly if it is needed to ensure your safety. Regardless of which handout and group you are assigned to, it will not affect your pre- and post-natal care.

8 Weeks After Delivery: You will receive an email 8 weeks after your delivery that will have a link to an online survey (should take approximately 10 minutes to complete). If no response is received electronically, you will receive a reminder email one week later. The survey will ask you about your demographics (e.g. education, age, race etc.), prior pregnancy history, attitudes on birth control, prior birth control use, and medical and surgical history. You are free to skip any questions you are uncomfortable in answering.

6 Months After Delivery: You will again receive an email 6 months after your delivery with an online survey (should take approximately 5 minutes to complete). If no response is received electronically, you will receive a reminder email one week later. The survey will ask you about your demographics (e.g., education, age, race etc.), prior pregnancy history, attitudes on birth control, prior birth control use, and medical and surgical history. You are free to skip any questions you are uncomfortable in answering.

This study is not meant to take the place of any medical or mental health treatment that you may want or need. During the study, we will not be monitoring your responses to the questionnaires in real time. This means that we will not be aware of any entries you make that could indicate health treatment is needed. If you are feeling depressed or suicidal, or are having difficulty coping with any aspect of your life, please contact your primary provider or go to your local emergency room as soon as possible.

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

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

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

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research.

4b. What are the possible benefits to others?

The results of this research will help determine the effect of educational handouts on birth control use after a woman delivers. A simple intervention like an educational handout may lead to better patient satisfaction and counseling efforts by healthcare providers.

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

You may choose not to be in this research study.

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

If you agree to take part, it will take you about 10 months (from the first survey to the last survey) to complete this research study. You will not need to return for any research-study-only visit to complete your part in the study.

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

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

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

In our research files at Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: Your name, address, phone number (if provided), email address, date of birth, medical record number, a code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Christina DeAngelis' office.
- Your research records will be labeled with your code number, your initials and your date of birth and will be kept in a safe area in Dr. Christina DeAngelis' research office.

For additional information ask the principal investigator or a member of the study team or contact the Human Subjects Protection Office at (717) 531-5687.

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

7b. What will happen to my research information and/or samples after the study is completed?

We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information we will remove any information that shows your identity.

7c. How will my identifiable health information be used?

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

The research team may use the following health information:

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

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

- PSH/PSU research staff involved in this study

- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Subjects Protection Office
- The PSH/PSU Research Quality Assurance Office
- Non-research staff within PSH/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original PSH/PSU records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

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

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

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

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health

information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

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

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

There will be no costs to you.

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

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

Upon completion of all three questionnaires, you will receive a $10 gift card after your 6-month questionnaire is submitted.

10. Who is paying for this research study?

The institution and investigators are receiving funds from the Penn State Hershey Medical Center OB/GYN department to support this research.

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

Taking part in this research study is voluntary.

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

If you decide to leave the research, please contact the researcher to inform them that you no longer wish to be contacted about your incomplete questionnaires.

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

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

Please call the head of the research study (principal investigator), Christina DeAngelis, MD, at (717) 531-3503 if you:

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

You may also contact the research protection advocate in the PSH Human Subjects Protection Office (HSPO) at (717) 531-5687 if you:

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

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

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

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

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

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

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

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

Signature of Person Giving Informed Consent and Authorization

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

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

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

Signature of Subject

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

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name