# Permission to Take Part in a Human Research Study

**Title of Research Study:** ***Advance provision of postpartum emergency contraception and its effects on reproductive autonomy: a mixed methods study***

**Investigator:** Dr. Ashley Turner, Department of OBGYN

**Supported By:** This research is supported by the Society of Family Planning

If your doctor is also the person responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

**Key Information:**
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

**Why am I being asked to take part in this research study?**
We are asking you to take part in this research study because you recently delivered a baby and you have not chosen to use a high-efficacy birth control method, which includes tubal sterilization, intrauterine device (IUD), contraceptive implant, and birth control pills.

**What should I know about a research study?**
- Someone will explain this research study to you.
- 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.
- You can ask all the questions you want before you decide.

**Why is this research being done?**
Emergency contraception (EC) is a medication that can be used after unprotected intercourse to prevent pregnancy. There are multiple types of emergency contraception available, and you may have heard of Plan B® or ella®. Though emergency contraception can be a good option for people who have episodes of unprotected intercourse, there are still some obstacles to patients using these medications. For example, though you can get Plan B® over the counter, you need a prescription for ella® (ulipristal acetate, UA). The purpose of this research is to look at the effects of giving postpartum patients an advance supply of ulipristal acetate (UA) before they leave the hospital. This study is interested in the effects of this intervention on EC knowledge, use, and feelings around reproductive autonomy, or feeling in control of your body. The medication used in this study is FDA approved for emergency contraception.

**How long will the research last and what will I need to do?**
We expect that you will be in this research study for 7-8 months if you complete the entire study.

You will be given a supply of 3 doses of UA prior to leaving the hospital. This advance supply of UA will be available for you to use at home if you feel you need EC. You will then be asked to

complete surveys (online, phone, in-person) at 6 weeks postpartum, 3 months postpartum, and 6 months postpartum. Each survey will take ~10 minutes to complete. If you have used emergency contraception by your 6 week visit, you will be asked to participate in a brief 20-30 minute interview on your experience. In your 6 month survey, you will be asked if you would like to participate in a ~1 hour long in depth interview around your experience in the study.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

**Is there any way being in this study could be bad for me?**
Like with any medication, there are possible side effects of taking UA. Most common side effects include disruption to your menstrual cycle and gastrointestinal symptoms, like nausea and bloating. However, these risks are **not** increased by being in this study. As this medication is FDA approved for emergency contraception, you may experience the same risks or side effects if you chose to take this medication outside of this study. Some people may feel uncomfortable or experience emotional distress from being asked or answering questions related to their sexual and reproductive health. It will be emphasized that you may stop the interview or decline to answer any question if you felt the need to do so.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

**Will being in this study help me any way?**
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include easier access to emergency contraception, possible prevention of unwanted pregnancy, and increased knowledge and awareness of emergency contraception methods.

**What happens if I do not want to be in this research?**
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

**Detailed Information:**
The rest of this document includes detailed information about this study (in addition to the information listed above).

**Whom can I talk to?**
If you have questions, concerns, or complaints, or think the research has hurt you, please email the study team at postpartumECstudy@gmail.com or call (872) 395-1184.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**How many people will be studied?**
We expect about 75 people will be in this research.

**What happens if I say "Yes, I want to be in this research"?**
If you choose to participate in this study, you will participate in a series of surveys and interviews. After completing the informed consent process, you will complete the initial baseline surveys. We will review contraceptive methods in general, including emergency contraception and discuss the reason why we recommend postpartum birth control and appropriate spacing between pregnancies. We will then discuss and counsel on what to expect with taking the study medication, ulipristal acetate (UA). You will receive 3 doses of UA on postpartum day one before you leave the hospital. You will be instructed to take a dose of UA if you have unprotected sex. Consenting to be a part of this study does not mean that you are obligated to take UA.

You will then complete surveys at 6 weeks, 3 months, and 6 months postpartum. These surveys can be completed online, via phone, or in-person based on your preference. If completed via phone, one of our study team members will call you and complete the study with you verbally. If in-person, the survey will be completed on paper in a private room in the same area as your OBGYN clinic (675 N St. Clair St, #200). Completing these visits should take ~10 minutes each.

If you have used EC by your 6 week visit, we will ask you to participate in a brief (20-30 minutes), in-person interview. After completion of your 6 month survey, we will also ask you to participate in an in-depth (1 hour) interview. Both of these interviews are optional and will be audio-recorded for data analysis. Agreement for audio to be recorded is required for participation in the interviews. Both interviews will be in-person and located in the same private room, mentioned above.

During this study, you will interact with members of the study team who have all undergone training around the study. You will only be interviewed by the Co-Investigator, Dr. Connie Lu.

This study will not take the place of or replace your usual postpartum care. For example, you should go to your routine postpartum visits as scheduled. Additionally, this study should not impact your healthcare decisions. For example, once enrolled, you can still participate in this study even if you decide to use a birth control method later on.

The following table describes the timeline of the study:

| Visit | Activity | Location | Duration |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Postpartum day one | Informed consent<br>Demographics and Reproductive Health Survey<br>EC Knowledge and Familiary Survey<br>Reproductive Autonomy Survey<br><br>Counseling on EC<br>Distribution of EC supply | Inpatient room | 30 minutes |
| 6 weeks postpartum | EC Knowledge Survey<br>EC and Contraceptive Use Survey<br>Reproductive Autonomy Survey | Online, via phone, in person based on preference | 10 minutes |
| *Optional* | *Brief interview* | *In person* | *20-30 minutes* |
| 3 months postpartum | EC Knowledge Survey<br>EC and Contraceptive Use Survey<br>Reproductive Autonomy Survey | Online, via phone, in person based on preference | 10 minutes |
| 6 months postpartum | EC Knowledge Survey<br>EC and Contraceptive Use Survey<br>Reproductive Autonomy Survey | Online, via phone, in person based on preference | 10 minutes |
| *Optional* | *In-depth interview* | *In person* | *1 hour* |

On completion of the study, you will be asked if you would like to be contacted for future studies by the investigators. If you decline, you will no longer be contacted by the study team after the study is concluded.

**What happens if I say "Yes", but I change my mind later?**
You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator. We may ask you your reason for withdrawing from the study, but you do not have to answer this question.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected data may not be removed from the study database. However, we will no longer access your medical record or other confidential records for the study after your decision to withdraw.

**Detailed Risks: Is there any way being in this study could be bad for me?**
UA is overall very well tolerated, but has possible side effects, similar to any medication. Common side effects include: headache (18%), abdominal pain (12%), nausea (12%), dysmenorrhea (9%), fatigue (6%), dizziness (5%). If you have any adverse effects, you can always contact our study team or your OBGYN clinic through telephone, MyChart, or in-person visit.

Psychological risks include potential discomfort or embarrassment with answering questions related to sexual activity and reproductive healthcare. You can refuse to answer a question if you are uncomfortable. An additional psychological risk is the possibility of pregnancy even with taking emergency contraception, which may be more unexpected for you if you are in this study.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

**What do I need to know about reproductive health and/or sexual activity if I am in this study?**
You are being asked to participate in this study because you would like to delay becoming pregnant for at least a year. While taking emergency contraception can be effective in preventing pregnancy after unprotected sex, becoming pregnant is still possible. If you become pregnant, you should contact the study team as soon as possible as you will need to be withdrawn from the study.

Ulipristal acetate has no known adverse effects on a pregnancy and has not been associated with congenital abnormalities. Additionally, it has not been shown that UA increases the risk of ectopic pregnancy. However, the research may hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

UA has no effect on breastfeeding, and there are no restrictions.

**Will it cost me anything to participate in this research study?**
Taking part in this research study will not lead to any additional costs to you.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

**What happens to the information collected for the research?**
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Certain topics, though we may not directly ask you about them, may be required by law or policy to report to authorities. This includes disclosure of child abuse, elder abuse, suicidality, and homicidality.

Data collected from the study will be retained after the study is completed for three years. Data will be securely stored on Northwestern Medicine server and is password protected. After three years, the data will be destroyed.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

**Data Sharing**
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Can I be removed from the research without my OK?**
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include pregnancy, significant adverse event, inability to follow up/lost to follow up. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

**What else do I need to know?**
If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you according to the table below for your time and effort. You will be paid upon completion of each activity.

| Visit | Type of activity | Compensation |
|---|---|---|
| #1 (6 weeks) | 10-minute survey | $10 |
| | Possible brief 20-minute interview | $20 |
| #2 (3 months) | 10-minute survey | $10 |
| #3 (6 months) | 10-minute survey | $10 |
| | Possible 1-hour in-depth interview | $50 |

Total possible compensation from this study is $100.

You will be issued the Stored Value Card (VISA), which is a type of bank debit card with a specific dollar value programmed into it. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card.

You will need to set a PIN to use the card at an ATM. Using the PNC automated service number and Account Access Code provided on the card, follow the prompts to establish a PIN. You may also call this number to obtain the current balance on the card and to verify your activity. A fee will be charged to speak to a live operator. This information can also be checked online at pncprepaidcard.com. Please note that neither PNC nor Northwestern can obtain the PIN if forgotten.

If the card is used at a PNC ATM, there is no fee; however, there will be a $2.50 charge for non-PNC ATM withdrawals. One card will be issued for the duration of your participation. If your card is lost or stolen, please call the study team on the contact information provided on this consent document.

Please be advised: You will incur a fee if the card is not used in 6 months and a monthly fee for each additional month of non-use. However, as long as there is activity (funds are added or card is used), on the card within 6 months the month period will reset and no monthly fee will be assessed. If the card is used at a restaurant, there will be a 20% "hold" above the tab amount. The card will be declined if used at a gas pump. Rather, the card must be physically presented to the gas station attendant.

**HIPAA Authorization**

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Name
- Phone Number
- Medical history

- Records about study medication
- Sexually Transmitted Illnesses
- Pregnancy
- Birth Control

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's).
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Study monitors and auditors who make sure that the study is being done properly,

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Ashley Turner
Institution: Northwestern Medicine
Department: Obstetrics and Gynecology
Address: 250 E. Superior St, Chicago, IL, 60

## Permission to Take Part in a Human Research Study

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

**Optional Elements:**
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

| **I agree** | **I disagree** | |
|---|---|---|
| _____ | _____ | The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team. |
| _____ | _____ | The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study. |

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent