**STUDY INFORMATION SHEET FOR**

# IN Control: Contraception Navigator Program

IRB 1801682245
Funded by the National Institutes of Health

**THIS STUDY'S LEAD RESEARCHER IS:**

Tracey Wilkinson, MD, MPH
Children's Health Services Research

**THIS STUDY'S EXPERTS ARE:**

Adolescents seeking contraception or people who work with people seeking contraception.
That means you!

**THIS STUDY'S GOAL IS:**

To pilot test our IN Control Program, which is a contraception navigator program for young people in Indiana.

Please follow these steps:

1. Read the study details below.
2. Decide if you want to be part of this study.
3. If yes, you will add your name, today's date, and email address. This research study is voluntary. It's up to you whether or not you want to take part. You can change your mind at any time. This won't affect your medical care or your relationship with Dr. Tracey Wilkinson or IU School of Medicine.

## Study details

**THINGS THAT WILL HAPPEN IN THE STUDY**

*Baseline Survey:* You will complete a survey online giving us some information about your experience getting birth control in the past and also with the help of the IN Control program. We will also collect demographics information (things like your name, race, gender, etc.) but this information is voluntary. Your name will not be tied to this information if we use it for presentations and publications. This survey should take ~15min to complete and you will receive a $20 gift card for your survey completion.

*Follow-Up Surveys*: You will complete a survey online giving us updates on your use of birth control, interactions with our program and other healthcare settings and updates to your medical history. We send these surveys 3mos, 6mos and 12mos after your first survey. Each survey should take ~10min to complete and you will receive a $20 gift card for each completion.

*Virtual Interview*: You will have a video call with a couple people from our team using a tablet, computer, or phone. During this interview, you will be asked some questions. The questions will be about your feedback on the IN Control program and things that worked and didn't work. This interview could take up to one hour, and you will receive $40.

**AUDIO & PHOTOS**

We will video/audio record the virtual interviews.

**POSSIBLE RISKS**

You may feel uncomfortable answering questions, completing study activities, or having the interviews audio or video recorded. There is also the potential risk of loss of confidentiality if someone finds out you are in the study, but we will do our best to keep your information safe as described below.

**POSSIBLE BENEFITS**

If you receive help from the IN Control program in obtaining a birth control method, that may be a benefit to you. However, there are no clinical benefits (like curing an illness or becoming healthier) to participating in the research part of the study. But you may find benefit in sharing your experiences or helping others.

**HOW YOUR INFORMATION WILL BE PROTECTED**

There is a small risk that your information could be "leaked" outside of the study team, but we are very careful to make sure that doesn't happen. For example, we will keep all papers and other study materials in a locked cabinet or office that only the study team can open. We will keep all study computer files on a password-protected server and only study staff will be able to get to it.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, any information that can identify you will be removed before being shared. Since you won't be able to be identified, we will not ask for your additional consent if we use information for future research.

**WILL I BE PAID FOR PARTICIPATION?**

If you participate in more than one portion of the study, you will be compensated after each portion.

- Surveys: $20 for each survey interview, up to $80 (baseline, 3mos, 6mos and 12mos)
- Virtual Interview: $40, up to $40

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

No, it will not cost you anything to participate in this study.

**WHO YOUR DATA MAY BE SHARED WITH**

When we share what we learned in this study, we will not use your name.

Your personal information may be shared to follow the law. For example, if you share that you or someone else is in danger or if you report ongoing child abuse or neglect, the law states that we must report this.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups

such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, The Agency for Healthcare Research and Quality, The Office for Human Research Protections, the National Institutes of Health, and any state or federal agencies who may need to access your medical and/or research records (as allowed by law).

The Indiana University Institutional Review Board or its designees may inspect your data to make sure we are doing our jobs correctly and protecting your rights. There are also state or federal agencies whose job it is to make sure the research we do is following the law. These agencies may need to access your research records (as allowed by law).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

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

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study contact the researcher, Dr. Tracey Wilkinson at 317-278-0552 or email tracwilk@iu.edu

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, you can contact the researcher at 317-278-0552.