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CONSENT FORM - Arm 1

Cross Organ Mechanisms in Chronic Pelvic Pain

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Sponsor: National Institute of Health

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The goal of this study is to understand risk factors and mechanisms responsible for menstrual and pelvic pain.
- **Duration.** It is expected that your participation will last for approximately 2 years.
- **Procedures and Activities.** You will be asked to participate in a 2-hour virtual study visit once a year for 2 years. This visit will involve a bladder filling task, the completion of questionnaires, and an optional tampon test. You will also fill out a diary tracking your period symptoms for 1 menstrual period.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include increased pain/sensitivity while undergoing the bladder filling task and potential sensitivity to certain questions being posed in questionnaires, such as those concerning childhood traumatic events.
- **Benefits.** There are no direct benefits to you but the researchers hope to learn about the relationship between menstrual pain, bladder sensitivity, and chronic pelvic pain.
- **Alternatives.** As an alternative to participation, you could visit a gynecologist to evaluate possible causes of menstrual pain. Participation in this study is voluntary.

Detailed Information about this Study:

Introduction: You are being asked to volunteer for this clinical research study because you have painful or non-painful menstrual periods.

Notably, our study is a research study, so our tests may not be clinically useful. This Consent Form gives information about the study that you can talk about with your doctor and/or family. You are being given this information to help your decision. If you have any questions, you can ask the study doctor and/or staff.

Why is this Study Being Done?

This study aims to understand the risk factors and mechanisms responsible for menstrual and pelvic pain. Although menstrual and pelvic pain are common, more research is needed to understand what causes these pain conditions. To understand what causes pelvic sensitivity, this study involves a natural bladder filling task, the completion of questionnaires, and an optional tampon test. This study does not include any treatments.

This study will include a total of 1050 subjects. Of those subjects, 1050 will be from NorthShore University HealthSystem (NorthShore).

What Will Happen During the Study?

If you agree to participate in this study, you will be asked to sign this consent form before any research-related activities are done. You will be asked to sign the form electronically using the REDCap website (a secure electronic system). Please print your name, sign your signature using a stylus or your finger, and date at the end of the consent form. Once signed you will have the option of downloading the form after you hit submit.

Diary Completion: You will be asked to complete a daily diary for at least 1 menstrual cycle to assess your pelvic pain, days you experience menstrual bleeding, and use of painkillers. Each daily diary should take at most 5 minutes to fill out. These will be completed online using any device connected to the internet. The daily diaries will be available for 90 days; if you do not fill out a daily diary for one complete menstrual cycle within the 90 -day period, we may remove you from the study. The research team will discuss this with you beforehand.

We will use the daily diary to determine if you are eligible to continue to the virtual assessment portion of the study. If you are deemed ineligible following a review of your diary, we will remove you from the study. The research team will communicate this to you should it be the case. If you are determined eligible to continue, you will be asked to provide the research team with your mailing address via REDCap. The research team will mail you instructions and materials for the virtual assessment.

Baseline Virtual Assessment: The virtual assessments will take approximately 2 – 2½ hours, and need to be completed on the luteal phase of your cycle (days 15-25, or any day without bleeding for those on oral contraceptive pills). You will not be able to complete the virtual assessment until you have received a mailing kit of supplies from our lab. Using the unique code in the mailing kit, you will log into REDCap to begin the assessment. You will be asked to avoid

taking short-acting over-the-counter painkillers (such as Advil/Ibuprofen and Tylenol/acetaminophen) for at least 6 hours before all study visits. For longer-lasting over-the-counter medications (such as 12 hour Aleve/naproxen), we will ask that you avoid taking them for 12 hours before the visits. We also will ask you not to take short-acting opioids (prescription painkillers such as hydrocodone and oxycodone) and caffeine for at least 6 hours before all bladder tests to allow for clear interpretation of the bladder testing. Participants with active gastrointestinal or genitourinary infections will have testing delayed until four weeks after recovery.

Bladder testing: We will ask you to complete a bladder test while filling out the questionnaires. We encourage you to drink lots of water beforehand as it will make the testing go by quicker.

It is important to try to remain seated as much as possible for this portion of the visit. At the start of the bladder test, we will ask you to go to the bathroom and urinate, so your bladder is empty. Using the measuring cup provided in your mailing kit, you will be asked then to drink 20 ounces of water within 5 minutes. You will also be asked to report one by one a) first sensation of need to urinate b) first urge to empty your bladder and c) maximum bladder tolerance before voiding. You may be asked to drink more water (up to 10 ounces) after both 45 and 60 minutes if you have not yet reached maximum tolerance at those time points. Once you reach maximum tolerance, you will go to the bathroom and urinate into a disposable measuring container included in the mailing kit. We will ask you to take a picture of the voided urine and either upload it to REDCap or text it to the research team before flushing it down the toilet.

If you do not reach maximum tolerance after 120 minutes the task will end, and you will be asked to void as described above.

Tampon Test (optional): You will be provided with a tampon in the mailing kit and asked to evaluate your sensitivity to temporary insertion of a standard tampon.

Questionnaires: The questionnaires in this study ask about any past and current pain symptoms and any medication you have taken for pain. We will also ask about your medical history, contraceptive history, sexual functioning, mental well-being, and traumatic childhood experiences. The links will be sent to your personal e-mail account via a secure Internet connection. To receive payment for the screen visit, you will need to complete all questionnaires within an appropriate time window; however, you may choose not to answer any questions that make you uncomfortable.

We may also ask you to sign a release form to obtain medical records related to prior testing or treatments for any pelvic pain issues from other doctors.

These questionnaires will take 30 to 60 minutes to complete and will be completed during the same 2 hour time frame as the bladder test.

Annual Virtual Assessments: We will ask you to repeat the virtual assessment once a year for 2 years after completing your baseline virtual assessment. These repeat assessments will consist of the same components as the baseline assessment: questionnaires, a bladder test, and an optional tampon test. You will receive an email notification once you are eligible to participate in an annual assessment. The research team will send you email reminders every 2 weeks until the assessment has been completed. If you do not follow the survey links and complete the

assessment within 6 weeks of sending, we may revoke access to the assessment; however, you will remain eligible to participate in the next annual assessment, if applicable.

In addition, you may also be asked to participate in in-person visits following your baseline virtual assessment if deemed eligible by the research team. These visits would occur over the same time period as the annual virtual assessments, and would offer additional compensation. Participation in these visits will require a separate consent form that explains the details of the visits. Please note that taking part in the in-person visits is completely optional, and you may opt to participate only in the virtual assessments described in this consent form.

During this study, the research team will collect information about you for the purposes of this research. We will collect data from your questionnaires and pain levels. Surgical and pain history (if relevant) may be abstracted from medical records.

This is an investigational study. The results obtained from the bladder test will not result in a clinical diagnosis. However, the data will allow scientists to understand menstrual and chronic pain mechanisms better.

How Long Will I Be in the Study?

It is expected that your participation in the study will last for approximately 2 years.

What Other Choices Do I Have?

This is a research study. The alternative is not to participate.

Are There Benefits to Taking Part in the Study?

There will be no direct benefit to you if you decide to participate in this study. You may indirectly benefit by feeling that you are helping people in the future. This study may allow doctors to learn more about menstrual pain, bladder sensitivity, and chronic pelvic pain and develop better ways to treat them in the future.

What Side Effects or Risks Can I Expect?

1. *Risk of study questionnaires:* Some of the questions you will be asked as part of the study may be personal in nature or upsetting or embarrassing. You can skip any questions you do not want to answer. If you feel you need to talk to someone not associated with the study about an issue distressing you, you can call 847-570-2500 to speak anonymously with a crisis counselor at NorthShore.
2. *Bladder testing:* Drinking the amount of water needed to complete the bladder testing may cause mild discomfort in your stomach, but it is not dangerous. This discomfort should be fully relieved at the end of the bladder test when you go to the bathroom.
3. *Security of study data:* Exposure of patient data with identifying information is a risk in any clinical investigation. The data management strategy used in this study is HIPAA compliant and utilizes a data isolation scheme separating identifying information from research-specific data. All data will be accessible only by authorized study personnel.

4. *Cessation of painkillers*: Subjects are asked to refrain from taking over-the-counter painkillers (such as acetaminophen, ibuprofen or naproxen) or short-acting opioids (ex. hydrocodone or oxycodone) for 6 hours before their study assessments (and longer for longer-acting painkillers, ~12 hours). The most common risk associated with this is inadequate short-term pain relief.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study and by the company paying for the research. Your research file can also be looked at by the NorthShore Institutional Review Board (IRB), other medical personnel at NorthShore who are involved in your care, or by the Food and Drug Administration (FDA).

Protected Health Information (PHI)

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “protected health information (PHI).” In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

What protected health information (PHI) will be used?

- Past, present and future medical records, including information housed in the Electronic Medical Record called “Epic,” which is maintained by NorthShore University HealthSystem
- Information about research procedures, including research office visits, medical tests, procedures, interviews and questionnaires

Who may see, use and share my PHI and why may they need to do so?

- NorthShore research staff involved in this study
- Non-research staff within NorthShore who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)
- The NorthShore IRB board that oversees the research and the NorthShore research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US government bodies that oversee or review research)
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- People or groups that we hire to do work for us, such as data storage companies, insurers and lawyers
- 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)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside NorthShore, we cannot promise that it will remain private.

Do I have the right to withdraw permission for the use of my PHI?

You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. Once permission is withdrawn, you cannot continue to take part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

Do I have access to my health information?

You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right *not* to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

Will I Be Paid for Participating?

You will be paid a sum of \$180.00 for being in this research study. You will be paid after each study assessment according to the following schedule: \$10 for completing the daily diary, \$40 for completion of the baseline virtual assessment, \$60 for completion of the 1st annual virtual assessment, and \$70 for completion of the 2nd annual virtual assessment. If you find the bladder testing intolerable and need to stop early, you will still be compensated.

For the daily diary, you will be paid via electronic gift card to Amazon.com. For the remaining study assessments, you will have the option to be paid via electronic gift card to Amazon.com, or be paid by check (or, if you are an employee of NorthShore Health, paid through payroll). If you do not complete the research study, you will only be paid for the length of time that you were a subject. You will be paid at the time you withdraw from the study.

Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study. You will still be responsible for all costs that you would normally incur as part of routine care.

What If I Am Injured During the Study?

If you become hurt or sick because of being in this research study, you can get medical treatment at NorthShore. You or your health insurance plan will be billed. No money has been set aside to

pay the costs of this treatment. You can ask for more information from the Research Institute of NorthShore.

Health insurance plans (including Medicare) may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Can I Withdraw from the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you can still get medical care as usual. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

Your doctor/the sponsor may stop this study or take you out of the study without your permission. If this happens, it might be the result of a bad reaction you have. There could also be new information that your doctor learns about the safety or helpfulness of this treatment.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224/364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

Who Can I Call with Questions?

The study doctor and staff will answer any questions you have via email at PelvicPainResearch@northshore.org. If you have additional questions at any time during the study, you may contact the Principal Investigator, Frank Tu, MD MPH, at telephone: 847-570-2521.

Optional Consent Questions:

Permission for Communication via Text

Do you give the research team permission to contact you about your study appointments via text messages? There is no way to protect ("encrypt") information in the messages sent by text. This means that information you send or receive by text message could be looked at by someone who was not supposed to see it, or by your mobile/cell phone provider or company. Therefore, when text messages are sent, there may be risks related to your privacy. We would like to use text messages to remind you about visits, send you links to surveys and give you other information

about the study. We will not send you any PHI via text. If you would prefer not to use texting, we will contact you via phone call or email.

Yes

No

Permission to Link Your Information Between Studies

May we link your data from the present study with data from any future studies you may participate in within our lab?

Yes

No
