Indiana University Informed Consent Statement and Authorization for Research
POCUS Utility in the Free Clinic Setting
IRB #29083

You are being asked to participate in a research study. This consent form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

Important Things to Know:

Why is This Study Being Done?

This study is designed to explore point of care ultrasound use in the free clinic setting. Point of care ultrasound is a frequently used tool in the hospital setting but access to the technology has limited its use in free clinics up until this point in history. The goal is to identify the ways it can be used effectively to better serve patients presenting to free clinics for care.

We are asking you if you want to be in this study because we believe ultrasound can be an effective tool to help in diagnosis and patient care. Based on your presenting symptoms, ultrasound may help us further diagnose your problem. The study is being conducted by Ian Oechsle, MD and Daniel Brenner, MD, through the Indiana University School of Medicine Department of Emergency Medicine.

How Many People Will Be in the Study?

You will be one of 50-100 participants taking part in this study.

What Will Happen During the Study?

- You will receive an ultrasound based on the issue that brought you to the clinic. This is not a mandatory part of your visit and would be in addition to the regular care you will receive. An ultrasound will take 5-15 minutes, may require you to expose one or more parts of your body for imaging, but this would take place in a private space as part of your clinic exam. The procedure is part of usual care for patients in a hospital but would not normally be used in this clinic.
- We will follow up with you by phone or email 30 days after your visit. You will not be required to have any specific follow up appointment.
- We will also collect information from your medical records as described below.

Your results will be discussed with you at time of completion of the ultrasound.

What Are the Risks of Taking Part in the Study?

- There are no known side effects to point-of-care ultrasound when performed in clinically indicated situations with a short duration of use.
- Someone outside the study team could get access to your research or medical information from this study.

What Are the Benefits of Taking Part in the Study?

Participating in this study may help your treatment team identify the cause of your symptoms. However, we don't know for sure. We are doing this research study to find out if this ultrasound helps or not.

Will I be Paid for Participating?

You will not be paid for participating in this study.

How Will My Information be Used?

The study team will collect information about you from your medical records. This may include information that can identify you, such as your name, contact information, and medical record number. Information from your medical records will be used to identify whether or not ultrasound was able to assist in reaching a formal diagnosis.

The information released and used for this research will include:

- Hospital discharge summary
- Radiology records
- Medical history/treatment
- Consultations
- Radiology films (like X-rays, CT scans, or formal Ultrasound)
- Laboratory/diagnostic tests
- Pathology reports
- Operative reports (about an operation)
- Diagnostic imaging reports

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians - Emergency Medicine
- IUMG - Primary Care Physicians
- Eskenazi Health
- Indiana Network for Patient Care (INPC)

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- State and Federal government agencies as permitted by law, including but not limited to The United States Food and Drug Administration (FDA)

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.

After your medical record information is released for purposes of this research study, your information may no longer be protected under federal privacy laws, such as HIPAA. However, your identifiable information will still be stored securely and only used as described in this consent.

Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information in this way, we will remove information that could identify you, such as your name and contact information, before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing.

How Will My Information be Protected?

We will do our best to keep your personal information private, but we cannot promise complete confidentiality. We won't share any information that we think could be used to identify you in publications about this study. However, your personal information may be shared outside the research study as described above and/or if required by law.

Who Should I Call with Questions or Problems?

For questions about the study, contact the researcher, Ian Oechsle, at 317-847-9594.

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 Research Protection Program office at 800-696-2949 or at irb@iu.edu.

What if I Do Not Want to Participate or Change my Mind?

After reviewing this form and having your questions answered, you may decide to participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your relationship with Indiana University or the medical care you receive from the Indiana University Student Outreach Clinic.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, your data will be removed from the research database stored on RedCap. If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Ian Oechsle at ioechsle@iu.edu. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsors, and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

Agreement to be Contacted by Text and/or Email

We would like to communicate with you about this study by text message and/or email. We might use text or email to check on how you are doing, or tell you about the progress of the research.

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, such as protected health information, could be accessed or read by someone other than you.

If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____

I authorize the researchers to send me emails related to this research study
Email address for this communication: _____

I authorize the researchers to send me text messages related to this research study
Phone number for this communication: _____

You can still participate in this study even if you do not want us to contact you by text or email.

Participant's Consent and Authorization:

I agree to participate in this research study.
Participant's Printed Name:
_____

Participant's Signature:
_____Date:_____

Participant's Address:
_____Date:_____
(include street address, city, state, and zip code)

Printed Name of Person Obtaining Consent:
_____

Signature of Person Obtaining Consent:
_____Date:_____