STUDY TITLE: UPPER ARM VS. FOREARM PLACEMENT OF EXTENDED DWELL CATHETERS: A COMPARATIVE EVALUATION OF BLOOD SAMPLING AND FUNCTIONALITY

This is a voluntary research study to find out more information about extended dwell us-guided IV catheter function that is placed in either the forearm or upper arm. This includes how many days the catheter is functional for use during a hospital stay. The study includes randomization, which is like a flip of a coin after you decide to participate, that determines if the IV is placed in either the upper arm or forearm. After placement of the IV, research staff will meet with you each day to assess the IV for as long as it is functional.

You do not have to take part to receive treatment and you may quit at any time.

There are risks to this study procedure that are described in this document. Some of the more common and/or serious risks include: pain, bleeding, or bruising at the insertion site: device damage or malfunction.

The potential benefit may be that the US guided IV catheter remains functional and fewer subsequent IVs need to be placed during your stay. However, there may be no direct benefit to you from taking part in this study. If you do not take part, or you withdraw from the study, you may receive the standard treatment and receive an US guided IV without participating in the study.

If you are interested in learning more about this study, please continue reading below.

CONSENT FORM AND AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION

STUDY TITLE: UPPER ARM VS. FOREARM PLACEMENT OF EXTENDED DWELL CATHETERS: A COMPARATIVE EVALUATION OF BLOOD SAMPLING AND FUNCTIONALITY

Principal Investigator: Amit Bahl, MD
Address: 3601 W. 13 Mile Rd. Royal Oak, MI 48073

Hospital:
☒ William Beaumont Hospital (Royal Oak, Troy and Grosse Pointe)

INTRODUCTION

Why is this study being done?

You are being asked to participate in a research study. The purpose of research is to look at the nature of disease and try to develop improved methods to diagnose and treat disease. The doctor or clinician in charge of the study believes you meet the initial requirements to take part in the study. Before agreeing to participate, it is important for you to read and understand the following explanation of the research procedures. This Consent and Authorization form describes the purpose, procedures, benefits, risks and discomforts of the study. It also describes the alternatives available to you, and your right to withdraw (quit) from the study at any time.

Please read this information carefully and ask as many questions as you like before deciding whether or not you would like to take part in this research study.

The goal of this study is to evaluate the differences in the length of time an ultrasound guided IV catheter remains functional when placed in the upper arm or placed in the forearm. A catheter is a flexible, sterile plastic tube which is inserted into a blood vessel using an ultrasound for guidance. An ultrasound is a painless imaging method that helps show the vessels under the skin using sound waves. Placement of the catheter is called intravenous or IV access and allows blood to be drawn or fluids or drugs to be given directly into the bloodstream. The catheter used in this study is cleared for use by the Food and Drug Administration.

A total of 96 patients will take part in the study at Beaumont Royal Oak in the United States.

How long will I be in the study?

If you decide to take part in this study, your participation is expected to last until you are discharged from the hospital but not more than 30 days.

DESCRIPTION OF THE STUDY

What will happen if I take part in the research study?

You are being asked to take part in this research study because you have been identified as needing an ultrasound guided IV catheter. An extended dwell catheter will be placed in either your forearm or upper arm using ultrasound guidance and is performed routinely for patients who need special IV access. During your hospital stay, you will be monitored for how well the IV is functioning.

If you agree to take part in this study you will be randomly assigned to one of two treatment groups. Randomization is like "the flip of a coin".

The treatment groups are:

A. Ultrasound guided IV placed in upper arm
B. Ultrasound guided IV placed in forearm

The following activities will occur at the specified study visits:
Screening:

- Medical history obtained
- Vital signs (blood pressure, heart rate, breathing rate)

Insertion:

- The ultrasound guided IV will be placed according to your assigned group. Measurements of the catheter will be taken with the ultrasound after placement.

During hospital admission:

- Every day following the placement of the IV until the IV is no longer functional, removed or until you are discharged, the IV and IV site will be assessed by a research staff member. This will include checking to see if the research staff can draw blood back from the catheter and flushing the catheter with 1 teaspoon of saline (5mL).
- Record the medications given through the catheter.

FDA Clinical Trial Information

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.

RISKS, SIDE EFFECTS AND DISCOMFORTS

Ask your doctor what the standard of care risks are as well as the study risks.

What side effects or risks can I expect from being in the study?

Most Frequent (occurring more than 10% of the time):

- Pain and bleeding
- Bruising at needle puncture site

Rare (occurring less than 1% of the time):

- Infection
- Blood clot

- Feeling lightheaded
- Fainting
- Air Embolism (air bubbles enter into blood and can travel to the brain, heart, or lungs)
- Guidewire or IV catheter embolism, or fragmentation (parts of the IV catheter insertion device break off, enter into blood and travel to other parts of the body)
- Catheter embolism
- Malfunction (IV catheter moves out of place in vein)
- Migration
- Nerve damage
- Thrombosis
- Fragmentation

There is a rare risk of breach of confidentiality (release of information which personally identifies you).

You will be informed of any significant new findings, which develop during the course of this research study, which may change your decision to continue participating in this study.

BENEFITS
What are the benefits of taking part in this study?
The potential benefit may be that the US guided IV catheter remains functional and fewer subsequent IVs need to be placed during your stay. However, there may be no direct benefit to you from taking part in this study. Information gained from the results of this study may be of benefit to others in the future, with a similar medical condition**.**

ALTERNATIVE OPTIONS
What are my choices other than taking part in this study?
You do not have to take part in this study to receive treatment for your condition.

ECONOMIC CONSIDERATIONS
What are the costs of taking part in this study?
There will be no cost to you for the study procedures described in this consent. Routine procedures you would have had done even if you were not taking part in this study will be billed to your health insurance company and/or group health plans as usual. If these routine care costs are not covered by your health insurance/group health plan, the cost will be your responsibility.

COMPENSATION
What happens if I am injured because I took part in this study?
Your involvement in this study is voluntary. The possible risks and side effects, which might occur during the course of the research study, have been described in this Consent and Authorization form.

A research injury is any physical injury or illness caused by the medications, devices, or procedures required by the study, which are administered, used, or performed appropriately.

These medications, devices, or procedures are different from the medical treatment you would have received if you had not taken part in the study.

Should you experience a research injury, there are no designated funds provided for subsequent medical care or compensation by either the study doctor/clinician or Beaumont.

What are my rights if I take part in this study?
You are not giving up any of your legal rights by signing this form.

CONFIDENTIALITY, DISCLOSURE AND USE OF YOUR INFORMATION
Will my medical information be kept private?
We will keep your personal health information as confidential as possible. It is not likely your information will be given to others without your permission. In order for this research study to take place, you must also authorize the researchers to access and use some of your protected health information (PHI). PHI is information, which could identify you as an individual such as name, address, date of birth, etc. By signing this Consent and Authorization Form, you give Beaumont permission to use and/or disclose (release) your health information related to this research. Your medical and billing records collected for the purpose of the study will remain confidential, but may be disclosed (released) or used by the following and/or their representatives:

- The investigators (study doctor/clinician, research staff)
- Beaumont and its' parent, Beaumont Health and affiliated hospitals
- The Food and Drug Administration
- Other governmental regulatory agencies (domestic and/or foreign)
- The study sponsor, BD/BARD
- Your health insurance company and/or group health plans and their intermediaries (companies contracted to process claims) may also have access to your medical and billing records of the study.
- Primary Care Physician

The purpose for this disclosure (release) or use is, for example, to assure compliance with the study protocol, to evaluate the effectiveness of the study, and/or to provide protection to you as a research study participant. The disclosure and use of your information will continue after your involvement in the study has ended. There is no expiration date for the use of your medical and billing records from the study. Any information about you disclosed to the parties identified above may be re-disclosed by them; however, such re-disclosure is not under the protections of this Consent and Authorization.

You will not be identified in any publication or other release of study results, data, and other information (such as in professional writings, at professional meetings, and in the study sponsor's product information, and/or advertising or other promotional materials).

If you decide to withdraw your authorization for the researchers to access and use your protected health information before the end of the study, you will be withdrawn from the research study. However, where the study relied on your Consent and Authorization for the

time you participated in the study, your Consent and Authorization cannot be withdrawn and the information already collected may still be used and disclosed as you previously authorized.

STOPPING STUDY PARTICIPATION

What if I decide to stop taking part in the study?

Taking part in this research study is completely voluntary. You may choose not to take part or to stop being in the study (withdraw) at any time without penalty or loss of benefits to which you are otherwise entitled, or without jeopardizing your medical care by your doctor at Beaumont. However, if you do not agree to sign this Consent and Authorization form, you will not be able to take part in this study.

If you decide to withdraw from the study you will need to notify the study doctor/clinician of your decision to stop taking part in the study. Written notification is preferred. This notice may be sent to Dr. Amit Bahl at Beaumont Royal Oak Emergency Center, 3601 W. Thirteen Mile Rd, Royal Oak, MI 48073.

Your participation in this study may be stopped by the study doctor/clinician or study sponsor, without your consent, for any reason, which will be explained to you. Examples include:

- The study medication or procedures appear to be medically harmful to you.
- You fail to follow directions for participating in the study.
- It is discovered you do not meet the study requirements.
- The study is canceled.
- It is determined to be in your best interest (for example, your disease has progressed despite treatment).

CONTACTS

Who can answer my questions about the study?

You may talk to the study doctor/clinicians about any questions or concerns regarding your study participation, or you think you may have suffered a research-related injury. The doctor/clinician in charge of the study is Dr. Amit Bahl, MD and may be reached at: 248-898-9111 to answer your questions.

Your contact person is Lauren Scribner, RN. You may contact her at (248) 898-5590.

If you have questions regarding your rights as a research participant, or have problems, concerns, complaints, want information or would like to offer input, you may contact the Institutional Review Board Chairperson at (248) 551-0662. The Institutional Review Board is charged with the oversight of all human participant research conducted at Beaumont facilities.

STATEMENT OF VOLUNTARY PARTICIPATION

I have read the above, have asked questions and have received answers about this study to my satisfaction. I understand what I have read and willingly give my consent to participate in **UPPER ARM VS. FOREARM PLACEMENT OF EXTENDED DWELL CATHETERS: A COMPARATIVE EVALUATION OF BLOOD SAMPLING AND FUNCTIONALITY.** I understand I will receive a signed copy of this document and will be promptly informed of any new findings regarding this study. I further authorize the use or disclosure of my health and personal information contained in records as described above.

_____
RESEARCH PARTICIPANT NAME (PLEASE PRINT)

_____ _____ _____
RESEARCH PARTICIPANT SIGNATURE DATE TIME

ALTERNATIVE SIGNATURE (for use only when participant is a minor, cognitively impaired or critically ill**)**
AS THE PERSONAL/LEGAL REPRESENTATIVE OF THE STUDY PARTICIPANT, PLEASE PRINT PARTICIPANTS NAME ON THIS LINE_____, AND CHECK ONE OF THE BOXES BELOW AS THE BASIS FOR YOUR AUTHORITY TO SIGN THIS CONSENT AND AUTHORIZATION:

☐ COURT-APPOINTED GUARDIAN
*COURT LETTER IS REQUIRED

☐ DURABLE POWER OF ATTORNEY
ATTORNEY LETTER MUST BE PRESENT & VERIFIED BY 2 PHYSICIANS

☐ NEXT OF KIN

_____ _____
NAME (PLEASE PRINT) RELATIONSHIP TO PARTICIPANT

_____ _____ _____
SIGNATURE DATE TIME

***WITNESS TO THE ENTIRE CONSENT PROCESS AND SIGNATURE ARE REQUIRED IF THE PARTICIPANT IS VISUALLY IMPAIRED, ILLITERATE OR NON-ENGLISH SPEAKING ONLY**

_____
WITNESS NAME (PLEASE PRINT)

_____ _____ _____
WITNESS SIGNATURE DATE TIME

AUTHORIZED CONSENT PROVIDER STATEMENT:

I have explained this study and have offered the study participant an opportunity for any further discussion or clarification.

_____ _____ _____
NAME (PLEASE PRINT) CREDENTIALS PHONE NUMBER

_____ _____ _____
SIGNATURE DATE TIME