

**The University of New Mexico Health Sciences Center
Consent to Participate in Research and HIPAA Authorization**

**Peripherally Inserted Internal Jugular Catheters:
an Observational Study**

February 20, 2018

What's this about?

We're asking patients having surgery, like you, to join a research study. It is being done by Dr. Tony Yen and his team. Up to 70 people will be in the study here at UNM.

We are studying a place to put your IV (intravenous line). That's the needle and tube that almost every hospital patient gets in their arm. Doctors use it to give you medicine and fluids. It usually goes in your arm, but other places can work too. Some people need a second IV to be ready in case the first one stops working. And for some people, it's hard for the doctor or nurse to find the right spot.

We're asking you to join our study because you need a second IV, or maybe because it was hard for the doctor or nurse to put in your first one. We're studying the idea of using a bigger vein, near the base of your neck.

This Consent Form explains our study and its risks and benefits. We want you to be happy with your choice about joining it. Please read carefully. Also, *please* ask questions like what we're doing, and what it might mean for you. We like to answer questions!

Do I have to do this?

No. You do not have to be in a study. If being in a study like this might make you or your loved ones upset, that's OK. You can just say no. Your surgery will go on as usual.

What would happen if I do this?

Signing this form means that you want to be in our study. If you do, we'll put a copy of this form in your medical record. Then these things will happen:

- We will get you ready for surgery just like normal.
- If it was hard to place your first IV, we'll put in this study IV *before* you have anesthesia.
- If the study IV will be your second one, we'll put it in *while* you are under anesthesia.
- Your doctor will carefully clean your skin where the IV will be placed.
- Your doctor will use an ultrasound machine to "see" the needle so it goes to the right place.
- Once your IV is in the right place, we'll put on the usual bandages to keep it in place.
- We'll measure how long it took to place your IV.
- Everything else about your surgery will be just like normal.
- You'll recover as usual after your surgery. We'll carefully take out your IV before you leave.
- We'll write down some things about you, your IV placement procedure, and whether it caused any problems.

Is there any risk?

Your surgery will not change at all for this study. But just like in any study, there are some risks. Being in a study could be stressful or make you upset. All IVs have rare risks of bleeding, infection, and blood clots, and this study does not change them. Because this large blood vessel is in the neck, there are rare risks of damage to a lung (pneumothorax) or to another blood vessel (carotid puncture). We'll use a needle of a certain size in order to make it less likely to accidentally hurt your lung. And ultrasound will let your doctor "see" the needle to help guide it into the right vein. There may also be unforeseen risks that we cannot predict. We will do our best to protect your personal information.

How would it help me?

If it was hard to place your first IV, using this larger vein may make it easier to place. For many people, using this larger vein means that your doctors can give you some medicines faster when needed. Having this IV ready might make it easier for your doctors to give you fluids and medicine when you need them. This IV might also be easier or faster to put in. If so, it could shorten the time you're under anesthesia. It could also reduce the pain that can happen when the doctors have to try more than once to put your IV in.

If I don't want to do this, what other choices do I have?

You don't have to be in this study. You can still have your surgery as usual. You will get all the usual care. Opting out of the study will not change the quality of care that you get at UNMH. Your doctors and nurses will still do their best to keep your IV lines clear and working well. Even if you don't join this study, you might still get an IV in this vein.

What if I get hurt or sick because I was in this study?

We have to tell you that the UNM Health Sciences Center (UNMHSC) cannot promise to give free medical care or money to people if they are hurt in this study.

If you do get hurt or sick because you were in this study, we would have to charge your insurance. If that happened, you might also have to pay more (maybe a copay).

Please tell us right away if you do get hurt or sick because you were in this study. If that happens, or if you think that we have treated you carelessly, please call the Human Research Protections Office at 505-272-1129.

Can I stop being in the study? Even after I begin?

Yes. You can change your mind at any time. If you want to get out of the study, just tell us. We can go back to using one of the regular places for your IV, if we haven't put it in yet. If you want to leave the study, we'll stop keeping records about you for it.

We also have the right to take you out of the study if we need to. This would only happen if we can't get information about you for some reason.

HIPAA AUTHORIZATION for use of your Protected Health Information

As part of this study, we will get health information about you. This information is protected because your name is on it.

Protected Health Information (PHI)

We don't want to waste your time. So while your doctors were getting ready to take care of you, they already checked your records to make sure that you could be in this study if you want. We're not asking people to be in our study unless they need a second IV or their doctors had a hard time putting in the first one.

Signing this Consent Form means that you will let us use more of your protected health information for the study. This includes things like your height, weight, and age; how long it took to place your IV, how well it worked, and whether there were any problems with it.

There may be times when the law says we have to share your information. This could be with the study sponsor, the legal system, federal and state regulators, or the UNM Human Research Review Committee (HRRC).

How will you keep my information safe?

Anything that could identify you will be kept in locked files for Dr. Yen's team only. We don't keep names on a computer for research. We only use study ID numbers like 1, 2, 3, and so on. Anything that could identify you will be destroyed when the study is over. We plan to publish our study's results, but we will not use your name. We also won't give your private information to any other researchers. We'll keep the information, without names, for several years.

Right to withdraw your permission

This form gives us your permission to use your information, unless you cancel it. We will use it as long as we need it for this study. However, you may take back this permission at any time. To do this, just send us a letter asking to be taken out of the study. Here's the address:

Dr. Tony Yen
Anesthesiology Department
MSC 10-6000
1 University of New Mexico
Albuquerque, NM 87131

Of course, we can't take back any information that we've already used or shared before we get that letter.

What if I don't want to sign?

If you choose not to sign this form, we won't include you in the study.

What if I have questions or complaints about this study?

You might have questions, concerns or complaints about this study. If so, you can call 505-272-2610 during normal business hours and ask for Dr. Yen. If you want to talk to someone else, you can call the UNM Human Research Review Committee (HRRC) at 505-272-1129. The UNM HRRC provides independent oversight of safety and ethical issues related to research involving human participants.

What are my rights as a research participant?

If you have questions about your rights as a research participant, please call the UNM Human Research Protections Office (HRPO) at 505-272-1129, or visit their website at <http://hsc.unm.edu/som/research/hrrc/>.

Consent and Authorization

You are deciding if you want to be in this study and let us use your information. You are not giving up any of your legal rights as a research participant. Your signature means that you read this form, or it was read to you. We will give you a copy.

My decision about joining this study:

*I have had a chance to ask questions, and all of them have been answered. Signing this Consent Form means that I agree to be in this study **and** give permission for my health information to be used or disclosed as described.*

Name of Participant (print)

Signature of Participant

Date

Witnessed by study team member:

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this form and freely consents to participate.

Name of Research Team Member

Signature of Research Team Member

Date