# INFORMED CONSENT DOCUMENT - NP

**Project Title: Intelligent Clinical Decision Support for Preoperative Blood Management**

**Principal Investigator:** Sunny Lou

**Research Team Contact:** Kristin Roles, 314-203-1909

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

## KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Sunny Lou having to do with evaluating a clinical decision support tool for preoperative blood orders. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not. Before you decide whether to be in this study, you may wish to consider other options that are available to you. Instead of being in this study, you could choose not to participate in this study and instead continue to complete your job duties as you normally would.

If you agree and sign this consent, you will be volunteering to participate in the research study, which will last for 1 year. As a voluntary participant, you will be asked to view a clinical decision support tool when you evaluate patients in the preoperative assessment clinic. You will be provided with training in how to use and interpret the tool. You will also have the opportunity to provide feedback on the tool. As part of the study, data on patients that you evaluate in the preoperative assessment clinic will be automatically collected from the electronic health record, including whether they had preoperative type and screen orders and whether they were transfused during surgery. Data will also be automatically collected on your use of the electronic health record, including whether you viewed the tool and orders that you placed. Your information will be kept confidential and will only be available to those who are working on the study.

The main risks to you if you participate are potential disruptions in your workflow related to viewing the tool. This study will help us understand how clinicians interact with clinical decision support tools, and may benefit future patients by finding high risk patients who might otherwise have been missed and by reducing unnecessary testing.

There is no cost to you to participate. You will receive Continuing Medical Education (CME) credit for your participation in the study. All of this information will be explained and is listed in more detail in

this consent document. The research team must give you a copy of this signed consent document.

The rest of this document provides more details about the study.

## WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you work in the Center for Preoperative Assessment and Planning (CPAP) at Barnes Jewish Hospital.

The purpose of this research study is to evaluate the effectiveness of a clinical decision support tool (S-PATH) designed to risk stratify patients for transfusion during surgery. Currently, we make decisions on which patients should have preoperative type and screen and crossmatch orders based solely on what procedure the patient is having; however, it is widely acknowledged that patient-specific factors also affect their risk of transfusion. The S-PATH tool aims to provide more personalized risk assessment of a patient's likelihood of transfusion, with the goal of ensuring that patients at risk for transfusion during surgery have appropriate orders, while avoiding unnecessary testing. This study aims to evaluate the effect of viewing S-PATH predictions on clinician ordering practices.

S-PATH is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

## WHAT WILL HAPPEN DURING THIS STUDY?

If you choose to participate, you will be randomized to either early or late access to the S-PATH tool.

Regardless of randomization group, during the first three months of the study, you will not have access to the S-PATH tool and you will continue to provide clinical care as usual, including use of the existing Maximum Surgical Blood Ordering Schedule to help determine which patients should have preoperative type and screen orders.

If you are in the early access group, you will start seeing tool predictions in the electronic health record (EHR) in the 4th month of the study.

- There will be a 1 month pilot period where you will be able to see S-PATH predictions but we ask you not to use it in clinical care. This pilot period is designed to get you accustomed to viewing and interpreting S-PATH predictions. We will provide additional 1:1 or small group training in how to view and interpret S-PATH appropriately during the pilot period. You will be asked to complete a survey on your opinions on the S-PATH tool at the end of the training. You will receive Continuing Medical Education credit for the training that you participate in.
- After the 1 month pilot period, we will ask you to start using S-PATH as part of your clinical work. However, you are in no way obligated to follow S-PATH's recommendations. Please continue to use your clinical judgement and the existing MSBOS as appropriate. The study team will be available throughout the study period for technical support and to address any questions or concerns that arise. You will continue to have access to S-PATH for the remainder of the study (8 months).

If you are in the late access group, you will start seeing tool predictions in the electronic health record in the 8th month of the study.

- There will be a 1 month pilot period where you will be able to see S-PATH predictions but we ask you not to use it in clinical care. This pilot period is designed to get you accustomed to viewing and interpreting S-PATH predictions. We will provide additional 1:1 or small group training in how to view and interpret S-PATH appropriately during the pilot period. You will be asked to complete a survey on your opinions on the S-PATH tool at the end of the training. You will receive Continuing Medical Education credit for the training that you participate in.
- After the 1 month pilot period, we will ask you to start using S-PATH as part of your clinical work. However, you are in no way obligated to follow S-PATH's recommendations. Please continue to use your clinical judgement and the existing MSBOS as appropriate. The study team will be available throughout the study period for technical support and to address any questions or concerns that arise. You will continue to have access to S-PATH for the remainder of the study (4 months).

At the end of the study, we will solicit additional feedback and opinions on the S-PATH tool via an interview and a survey. You do not have to participate in these activities and you are free to skip any survey questions you would rather not answer. You will receive Continuing Medical Education credit for your time if you choose to participate in these activities. If you participate in the interview, you will be audio-recorded for transcription purposes. You will receive an email with an invitation to complete the survey and sign up for an interview; we may send you up to 5 reminder emails

Results of this study will be presented at a CPAP education meeting after the end of the study. As part of your participation in this study, we will be collecting information on the patients that you see in CPAP clinic, including whether any type and screens were placed by you or any subsequent clinicians (e.g., day of surgery teams), whether the patient received any red cell transfusion during surgery, and whether the patient had any transfusion reactions. We will also be collecting your demographic information, if you choose to provide it, and information on how you use the electronic health record to measure how often you viewed the S-PATH tool during the time periods you had access to the tool, and information about your typical clinic assignments and work schedule. All of this information will be collected automatically from existing information in the electronic health record. All information will be stored in a password-protected secure location that only members of the study team can access.

**Will you save my research information to use in future research studies?**

The data we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, other research centers and institutions, or private companies involved in research.

We may also share your research data with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies and other researchers. If your individual research data is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

These future studies may provide additional information that will be helpful in understanding the effectiveness of clinical decision support tools, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. Should this occur, there are no plans to provide financial compensation to you. There are no plans to provide financial compensation to you should use of your data occur. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your data you give up any property rights you may have in the data. We will protect the confidentiality of your information to the extent possible.

Your data will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

**Audio Recording**

If you choose to participate in the interviews at the end of the study, audio recordings will be made of the feedback. Your feedback will be used to improve the S-PATH tool for future users. Your audio recordings will only be used to generate transcripts of the feedback you provide, and will only be accessible to the study team. The audio recordings will be destroyed once the study is published or within 5 years, whichever is sooner.

While all recordings are stored in a confidential manner, please be aware that it may be possible to identify you from your voice recording.

I give you permission to make audio recordings of me during this study.

**_____ Yes** **_____ No**
**Initials** **Initials**

**HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 60 people will take part in this study conducted by investigators at Washington University.

**HOW LONG WILL I BE IN THIS STUDY?**

If you agree to take part in this study, your involvement will last for 1 year. As described above, you will have access to the S-PATH tool for either 8 months or 4 months within this year. We will provide 1 hour of training on the use of the S-PATH tool before you start using it. At the end of the study, we will solicit additional feedback on the tool; you do not need to participate in this, but if you do, it will take no longer than 1 hour. Data will be collected for all patients that you saw during the study period, even if their surgery was outside the study period.

## WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

**Risk of disruption to clinical workflow**. Use of the S-PATH tool may slow down clinic workflow. To minimize this risk, we have carefully designed the S-PATH tool in collaboration with CPAP leadership and nurse practitioners who work in clinic along with other stakeholders (anesthesiologists, surgeons) to align the S-PATH system with clinician workflow and make it easy to use. There will be a pilot period where the tool is not actively used, and we will provide personalized training in S-PATH use to reduce the burden of learning a new workflow. In addition, S-PATH use will be optional. Contact information for the study team will be provided to you so that technical issues and concerns about workflow impact can be promptly addressed.

**Risk for patients requiring intraoperative transfusion in the absence of presurgical blood orders**. If the need for transfusion is urgent to protect patient safety, emergency release blood can be administered. Emergency release blood is currently available within all of the operating room areas at Barnes Jewish Hospital, and can be retrieved within 5 minutes. It is already routinely utilized for this purpose, i.e., for patients encountering unexpected surgical bleeding where the time to obtain crossmatched blood exceeds clinical need. Anesthesiology clinicians who provide intraoperative care will be notified of this study, and additional educational materials will be provided about the availability of emergency release blood prior to study initiation. The frequency of emergency release blood utilization and adverse events associated with transfusion will be monitored and reviewed by the Data Safety Monitoring Board (DSMB) to ensure patient safety.

**Breach of Confidentiality**
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

## WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

You will receive Continuing Medical Education credit for the time you spend learning how to use the S-PATH tool and providing feedback on tool use. You can receive up to 5 CME credit-hours.

## WHO IS FUNDING THIS STUDY?

The National Heart, Lung and Blood Institute (NHLBI) is funding this research study. This means that Washington University is receiving payments from NHLBI to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NHLBI for conducting this study.

## HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Heart, Lung and Blood Institute (NHLBI)
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The Data Safety Monitoring Board (a committee comprised of external researchers that oversees the safety of human participants in this study). The Data Safety Monitoring Board will meet twice during the study to ensure the safety of study subjects.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will store all study information in a secure password-protected location that only the study team has access to. After the study is over and the data is analyzed, any potentially identifying information will be replaced with anonymous identifiers prior to the data being deposited as required by the National Institutes of Health.

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.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

## IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

### What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

If you decide to leave the study early, we will ask you to contact the study team in writing by email using the contact address provided at the top of this document. There will be no consequences for leaving the study early.

If you withdraw from the study we will ask your permission to continue to follow what happens to patients who you saw when you were enrolled in the study. This information will be automatically collected from existing electronic health record data.

### Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

### Can someone else end my participation in this study?

Under certain circumstances, the investigator or the study sponsor might decide to end your participation in this research study earlier than planned. This might happen for no reason or because the Data Safety Monitoring Board has identified human subjects concerns or because funding for the research study has ended.

## WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Sunny Lou, slou@wustl.edu, 314 374 0300. If you experience a research-related injury, please contact: Kristen Roles, 314-203-1909.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

---

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

**Do not sign this form if today's date is after EXPIRATION DATE: 09/01/26.**

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

**Statement of Person Who Obtained Consent**

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)