COVER PAGE

Title: **A Prospective, Randomized, Parallel-group Single Center Study to Evaluate the Use of Thromboelastometry (ROTEM) in Patients Undergoing Spine Surgeries.**

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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**A Prospective, Randomized, Parallel-group Single Center Study to Evaluate the Use of Thromboelastometry (ROTEM) in Patients Undergoing Spine Surgeries**
Principal Investigator:	**Galina T. Dimitrova, M.D.**
Sponsor:	**Department of Anesthesiology, The Ohio State University Wexner Medical Center**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, 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 usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

Patients undergoing spine procedures are at an elevated risk for blood loss during surgery. The purpose of this study is to compare two standard approaches for assessing blood loss needs. Currently, most spine surgeries in the U.S. use laboratory testing to evaluate intra-operative bleeding and guide blood transfusion (blood administration) during surgery, when needed. These laboratory tests provide your doctor specific information regarding your blood composition and clotting ability. After these blood samples get collected, they are sent to the hospital laboratory for analysis. This process typically takes around 30 minutes to complete. A newer machine, called a Rotational

Thromboelastometry (ROTEM) device, is also standard of care at our institution to perform these same tests. The only difference is that this device is available in the operating room (OR) and provides results almost immediately. Therefore, the ROTEM has the prospect of improving testing turnaround time. The use of hospital laboratory or the ROTEM device is interchangeable, and it's left to the anesthesiologist's criteria. Only a limited amount of comparison has been done between these two approaches. This research will compare both approaches and allow physicians to develop better decision-making models for future patients undergoing spine procedures. Ultimately, this may advance patient care and improve the guidelines for blood transfusion.

2. How many people will take part in this study?

A total of 110 patients will take part of this study.

3. What will happen if I take part in this study?

If you decide to participate, you will be randomly assigned (like flipping a coin) to either the laboratory testing or ROTEM. You have a 50/50 chance of being assigned to either approach. According to which group you are assigned to, your transfusion needs will be managed as follows:

Group 1: Laboratory testing:
If you are assigned to the laboratory testing approach, your anesthesiologist will assess any blood transfusion needs according to the hospital's standard guidelines. This will require approximately 5 mL (one tablespoon) of blood to be taken from you, which will be sent to the hospital's laboratory for processing and analysis. These results are usually available in about 30 minutes. Your anesthesiologist will receive your test results by phone or they will be uploaded to your electronic medical record. At which point, he/she will determine if a blood transfusion is necessary. These blood tests will be performed every hour, or according to your anesthesiologist's discretion.

Group 2: Rotational Thromboelastometry Test (ROTEM)

If you are assigned to the ROTEM approach, your anesthesiologist will assess any blood transfusion needs according to the specifications of the ROTEM machine. This device will be located in the operating room (OR), right next to your anesthesiologist. Approximately 5 mL (one tablespoon) of blood will be taken, which will be processed and analyzed immediately in the OR. Test results will be available within a few minutes. This will occur every two hours, or according to anesthesiologist's judgment. Results will be displayed on the monitor in real-time.

Please note that no changes will be made to the surgical or anesthesia care you receive as part of your participation in this study. The comparison between the laboratory testing and

the ROTEM approaches is being conducted to determine whether one is favorable over the other.

After your surgery is over, we will be collecting information from your electronic medical record for the first 24 hours. This information will include: the need of blood transfusion after surgery, and any complication you have after surgery. We will also check the length of your hospital stay, even if greater than 24 hours. A phone call 30 days after your surgery will also be performed to check if you have had any complication after your surgery, and your overall health status.

4. How long will I be in the study?

Your participation will last approximately 30 days. Participation will start once you sign consent and conclude after the 30 day follow-up phone call.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There is no foreseeable health risks associated with your participation in this study. If you are randomized into the ROTEM approach, there is a slight risk that the ROTEM device malfunctions during surgery. If this occurs, your anesthesiologist will proceed with using the laboratory testing approach and the ROTEM device will no longer be used.

7. What benefits can I expect from being in the study?

You may not directly benefit from this study. Both approaches are commonly used in the U.S., therefore surgical and anesthesia care will not be affected by your participation in the study. The results of this study may assist in developing better transfusion guidelines in future spine patients.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you have any questions regarding alternatives to coagulation testing or blood transfusions, you are more than welcome to speak with your anesthesiologist.

9. What are the costs of taking part in this study?

There are no additional costs associated with participating in this study.

10. Will I be paid for taking part in this study?

You will not be paid for being a part of this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.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 the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition
- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact

Galina T. Dimitrova, MD
The Wexner Medical Center at the Ohio State University
Department of Anesthesiology
410 W 10th Ave.
Columbus, Ohio 43210
Office: 614.293.7282 / 614.293.3559
24 hours: 614.293.7243 (ID# 0265)
Galina.Dimitrova@osumc.edu

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact

HIPAA Privacy Officer
The Ohio State University Wexner Medical Center
Suite E2140
600 Ackerman Road
Columbus, OH 43210
614-293-4477

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact

Galina T. Dimitrova, MD
The Wexner Medical Center at the Ohio State University
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Columbus, Ohio 43210
Office: 614.293.7282 / 614.293.3559
24 hours: 614.293.7243 (ID# 0265)
Galina.Dimitrova@osumc.edu

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	_____ **AM/PM**
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	_____ **AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	_____ **AM/PM**
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	_____ **AM/PM**
	Date and time
Printed name of witness	**Signature of witness**
	_____ **AM/PM**
	Date and time