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

Study Title: A pilot study of using statins in patients with acute venous thromboembolism

Principal Investigator: Tzu-Fei Wang

Sponsor: The Ohio State University Wexner Medical Center Department of Internal Medicine

- **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 who have had blood clots in their leg veins (deep vein thrombosis, DVT) can have long term problems after their initial blood clots, such as chronic swollen and painful legs called post-thrombotic syndrome or the blood clots could come back. How to decrease these long term problems is not well-known.

Statin drugs are commonly used medications to treat high cholesterol and heart diseases. Some evidence showed that statin drugs can potentially help prevent blood clots from coming back. However, how they work is unclear.

In this study, we will study the role of statins in patients with new DVT, by measuring important blood tests in patients who are taking blood thinners with or without statins as treatment for their DVT.

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

We plan to enroll 80 people in this study at OSU.

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

If you decide to take part in this study, you will be randomly assigned (like the flip of a coin) to one of two groups. You have an equal chance of receiving blood thinners alone or blood thinners plus atorvastatin, a commercially available statin drug. You and your treating doctors will know which group you are in, and side effects from both atorvastatin and the blood thinner will be discussed with you and closely monitored.

You will also be asked to give a sample of your blood at three time points: at enrollment, 3 months later, and 9 months later. The 3-month and 9-month blood collection will occur in conjunction with your regularly scheduled follow-up visits for your DVT. On average, these visits last 1-2 hours. The research procedures during these visits will only last 10-15 minutes. A total of 40 mL (8 teaspoons) of blood will be obtained at each visit (half are for standard laboratory tests and half are purely for research purposes). We ask that you fast for 9 hours prior to these blood draws. Your blood sample will be assigned a number, and no personally identifiable information will be shown on your sample. At each visit we will also ask you about any medications you are taking or have started to take in the time between visits. For your safety, participants may only take warfarin or rivaroxaban to be included in this study. Thus, you should remain on the drug you are randomized to throughout your time on anticoagulation and not switch to other oral anticoagulants during the study period.

If you are a woman of childbearing potential, a urine pregnancy test will be done at the initial visit, the 3 month visit, and the 9 month visit. You cannot be in this study if you are pregnant. If you become pregnant while you are in the study, you will no longer be able to participate and you will be excluded from the study.

A Doppler ultrasound of your legs will be done at the 3 month visit as typically done for your type of blood clot. A Doppler ultrasound is used to measure the flow of blood through your blood vessels using high-frequency sound waves. You will lie on a cushioned table and gel will be applied to your skin. A hand-held device that sends and receives ultrasound signals will be moved over your legs. This will take approximately 30 minutes.

Your blood samples will be sent to participating laboratories at Nationwide Children's Hospital (NCH) for the study related blood tests. Some of your blood samples will be sent to the Blood Center of Wisconsin (BCW) for analysis. The sample will be coded, meaning no personally identifiable information will be sent with your blood to NCH or BCW.

4. How long will I be in the study?

You will be in the study for a total of 9 months from the time of study participation. If you are assigned to the atorvastatin group, you will need to take atorvastatin for 9months (it may be stopped early if side effects happen but you will be able to remain in the study). Your doctors will monitor you and obtain necessary blood tests for the rest of the time, even after stopping atorvastatin and/or blood thinners.

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, you can call the study coordinator Melanie Heinlein at 614-293-5176 to request to be taken off 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.

If you decide that you no longer wish to have your samples stored, the research lab will discard all of your stored samples and no further research will be done with the samples.

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

Statin drugs, while commonly used for other diseases, can cause some side effects, including elevation of liver enzymes, muscle soreness and pain, joint pain, headache, nausea and rarely, severe muscle damage leading to kidney failure. However, this is very rare (less than 1%) and more commonly happens with a higher dose of statins compared to the amount that is given for the study. You and your doctor will know if you are going to be taking the statin drugs or not, which will allow close monitoring of these symptoms and early intervention if needed to be.

Taking blood from a vein may cause some pain, infection, bleeding, or bruising at the needle stick site, and rarely cause fainting. Blood tests for this study will be done at the same time as routine blood draws whenever possible. The total amount of blood needed for this study is about 24 teaspoons, which will be separated into three time blood drawn 3 months and 6 months apart (8 teaspoons at each visit), so this amount will not harm you in any way.

The other risk is the violation of patient confidentiality. We will assign a number to your blood samples, not your name. This will allow researchers to relate clinical information to the laboratory data without violating your confidentiality. In addition, while results from this study are intended to be published in the future, you will not be identified in any manner in publications or presentations that could arise from this work. Any future discoveries arising from these studies which could potentially impact the treatment of your disease will be discussed with you. You will be told of any new information that may influence your willingness to continue to participate in this study.

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

You may not have direct immediate benefits from being in the study. However, by studying important blood tests and their changes during the time course of DVT, and the potential benefits of these commonly used, well-tolerated statin drugs, we can understand the disease of DVT better and identify better treatment for it to prevent long term complications. In the future, patients with DVT can be treated more effectively.

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.

9. 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).

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 records. 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.

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.

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

There are no direct costs of taking part in this study. However, the medications (anticoagulation), routine medical care, laboratory tests, and imaging studies for the routine care of your DVT will be billed to your insurance company and you may be responsible for co-payment (if needed as dictated by your insurance plan). Since statins are not currently considered routine care for patients with blood clot, it may not be covered by your insurance company, and the cost of statins if you are assigned to the statin arm will be reimbursed to you by the study, so you will not have extra cost to participate in the study.

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

Yes, you will be given a $6 dollar food voucher to be used in the cafeteria for each of the scheduled study visit (enrollment, 3 and 9 months) to compensate your efforts of fasting prior to laboratory tests.

12. 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 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.

13. 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.

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;
- Records about any study drug you received;

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 you may contact the coordinator for the study ***Melanie Heinlein at 614-293-5176.***

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact ***HIPPA Privacy Officer, Suite E2140, 600 Ackerman Road, Columbus, Ohio 43202,*** or by phone at ***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 ***Dr. Tzu-Fei Wang at 614-293-9441.***

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 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

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