The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:	Physical Activity in Children at Risk of Post-thrombotic Syndrome: A Pilot Randomized Controlled Trial
Funding Agency/Sponsor:	Children's Clinical Research Advisory Committee (CCRAC) National Institutes of Health (NIH)
Study Doctors:	Ayesha Zia, MD

You may call these study doctors or research personnel during regular office hours at (214) 456-2382. At other times, you may call them at (214) 456-7000.

Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the "you" in this document refers to the minor.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to test how practical and useful a personal "fitness tracker" is in improving children's adherence to an activity regimen following an initial deep vein thrombosis (DVT) or pulmonary embolism (PE). Physical activity will be studied as a way to prevent Post thrombotic syndrome (PTS).

Why is this considered research?
This is a research study because we do not know if the use of activity trackers will improve adherence to an exercise regimen aimed at preventing PTS.

The following definitions may help you understand this study:

- Randomization means you will be placed by chance (like a flip of a coin) in one of the study groups.
- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Researchers means the study doctor and research personnel at the University of Texas Southwestern Medical Center at Dallas and its affiliated hospitals.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have been diagnosed with a first time deep vein thrombosis and you have completed approximately 12 weeks of treatment for your blood clot (for example, heparin or Coumadin).

Do I have to take part in this research study?"
No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?
About 44 people will take part in this study at Children's Medical Center.

What is involved in the study?
If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for the purpose of this study.

The following definitions will help you better understand the abbreviations or terms in the section below:

- SOC procedures – standard of care procedures -tests you will have for your regular care even if you do not participate in this research study
- PTS (Evaluation) – PTS stands for Post-thrombotic syndrome. This evaluation will look for signs and symptoms of PTS, such as chronic leg pain, swelling, redness;
- QOL forms – Quality of Life forms. These forms will collectively capture information on DVT and PTS symptoms and measure quality of life (Physical, Emotional, Social, School) from your (patient's) perspective;
- ECS log – elastic compression stocking log;
- Anticoagulation – therapy for your deep vein thrombosis such as heparin or

Coumadin

Screening Procedures

To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.

You may also have to fill out certain forms or have the following exams, tests or procedures:

Screening/Baseline - collected as standard of care (SOC):

Once the informed consent form has been signed, we will collect the following information:

- Detailed medical history;
- Detailed physical exam results;
- Review of existing medical records
- Laboratory results;
- Current medications;
- Imaging results of your venous thromboembolism (VTE);
- Assessment of Post-thrombotic syndrome (PTS);

Procedures and Evaluations during the Research

All study visits will coincide with your standard of care visits related to your VTE.

Study Medication/Intervention-Group Assignment

If the researchers believe you can take part in this study, you will be assigned randomly (like a flip of a coin) to either

1) Standard care or control arm which includes a 15-20-minute education session on PTS and the benefits of enhanced activity after DVT.
   or
2) Intervention Arm which includes a standardized 15-20-minute education session on PTS and the benefits of enhanced activity after DVT and wearing a Fitbit to measure activity.

You have a 1 in 2 chance of being placed on the Fitbit or control arm.

The group you will be in is decided by a web-based program. Neither you nor the researchers will be allowed to choose which group you are assigned to.

Procedures and Evaluations during the Research

All participants will have the visits coincide with their regular standard of care visits. After consent, you will complete an activity log for 16 weeks and may or may not wear a Fitbit.

Intervention Arm:
If you are randomized to the intervention arm you will receive a Fitbit, a standardized 15-20-minute education session of PTS and the benefits of increased physical activity. You will be asked to wear the Fitbit for 16 weeks.

(1) The first 4 weeks you will be asked to continue your everyday activities to establish your baseline or normal level of activity.
(2) A "target steps/day" will be calculated to increase your level of activity by 25%. You will be asked to maintain your target level of activity for 8 weeks. During these 8 weeks, if you struggle to keep your "target steps/day" or need extra help on how to use the Fitbit, a face-to-face session will be arranged with the study research coordinator and a physical therapist.
(3) The last 4 weeks you will be allowed to keep aiming for your "target steps/day" or return to your normal level of activity.
(4) Your number of steps taken, distance travelled, calories burned and heart rate with activity will be uploaded to the Fitabase.
(5) You will receive a phone call at least once a month to see how you are doing and remind you to complete and return the activity logs.

A phone call or face-to-face session may be arranged with the study research coordinator and physical therapist if you experience any difficulty with using your Fitbit.or the FItabase.

You will not get to keep the Fitbit at the end of this study. It will be returned to the study center at your Visit 2.

Control Arm:
If you are randomized to the control arm, you will receive a standardized 15-20-minute education session on PTS and the benefits of increased physical activity. Your physical activity will be self-recorded in an activity log throughout the 16 week intervention period. You will receive a phone call once a month to see how you are doing and remind you to complete and return the activity logs.

Both Groups:
Regardless of which arm you get assigned to, you will also be asked to record the following information:

- all medications (if on Rivaroxaban and Xarelto) taken each day,
- all activities completed, and
- wearing of elastic compression-stocking (ECS)

These logs will be returned at the follow-up visits.

You will be given the PedsQL, a 15-minute questionnaire that measures health related quality of life in adolescents, at all visits.

You will have about 1 ½ teaspoons of extra blood collected at Visits 1,2, and 3 (for a total of about 4.5 teaspoons) for biomarker testing because you are in this study. The biomarkers testing will test for markers that show how your body breaks down blood clots. Blood will be collected as standard of care procedures for Factor VIII, D-dimer, and C-reactive protein. These studies will measure how your blood clots. If the Factor VIII, D-dimer, and C-reactive protein results were normal at Visit 2, the costs of those tests can be covered as research instead of standard of care.

You will have a Doppler ultrasound completed at the end of your anticoagulation therapy as part of your standard medical care.

In the table below:
R = procedures that are done for the research;
S = procedures that are done as part of your standard of care

Table 1: Study Procedures for Each Visit

	[1]Visit 1(after 2-3 months of therapy; 2-3 hour long)	[1]Visit 2(approx. 4 months after Visit 1, 2-3 hour long)	[1]Visit 3(approx. 2 months after Visit 2, 1-2 hours long)
ALL PARTICIPANTS			
Informed Consent	R		
Full Medical History	S	S	S
Physical Exam	S	S	S
Laboratory Testing	S,R	S,R	S,R
QOL forms	R	R	R
PTS evaluation		S	S
ECS log	R	R	R
Activity Log/Questionnaire	R	R	R
Medication log[2]	R	R	R
Phone Calls (MONTHLY)	R	R	
Formal Education Session	S		
Clincard Payment	R	R	R
FITBIT ARM			
Hands-on session on Fitbit use	R		
Steps/day data (weekly)	R	R	
Return Fitbit			R

[1]The time estimation given for Visits 1, 2 and 3 are for research and standard of care (SOC) procedures. All efforts will be made to streamline research and SOC procedures so that your time in clinic will be as short as possible.

[2]Medication logs will only be collected for participants on Rivaroxaban or Xarelto.

How long can I expect to be in this study?
You will be in this research study for about 9 months.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?
Psychological Stress
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality
Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks of Blood Drawing
Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely.

You will have about one and a half teaspoons of extra blood collected at Visits 1 and 2 (for a total of about 3 teaspoons) because you are in this research study.

Risk of Doppler Ultrasound
There are no risks from the sound waves used for ultrasound. The test is not painful and does not have any radiation. This will be done as per standard of care.

Other Risks
There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

Study Procedure/Intervention
Because of your participation in this study, you may be at risk for injuries or falls related to more exercise or physical activity.

How will risks be minimized or prevented?
Potential risks and discomforts will be minimized by using staff that are trained in treating people with blood clots. Monitoring for adverse reactions will be performed throughout your participation in this study. Blood samples collected for this research study will be collected at the same time as your standard of care labs – this will

minimize the risks associated with blood collection.

What will my responsibilities be during the study?

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Report to the researchers any injury or illness while you are on study, even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?

If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

What are the possible benefits of this study?

If you agree to take part in this study, there may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with blood clots in the future. Information gained from this research could lead to better care and monitoring for patients with blood clots.

What options are available if I decide not to take part in this research study?

This is not a treatment study. You do not have to be part of it to get treatment for your condition.

Will I be paid if I take part in this research study?
Yes. You will be paid for your participation in this research. The amount you receive will be based according to the following visit completions and the return of the Fitbit (if applicable), activity, medication, and compression use (if applicable) logs:

- Visit 1 or Baseline visit - $25
- Visit 2 or Week 16 visit - $25
- Visit 3 or Exit visit - $50

There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

How will I be paid?
You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. You will also receive instructions on how to use the card. In order to receive study payments, your name, address, date of birth and Social Security Number (SSN) will be collected from you by the research staff. All information will be stored in a secure fashion and will be deleted from the UT Southwestern Greenphire ClinCard system once the study has been completed.

Important Information about Study Payments

1. Your SSN is needed in order to process your payments. Should you decide not to provide your SSN, your study participation payment will be decreased at the current IRS tax rate. Study payments are considered taxable income and are reportable to the IRS.
2. An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.
3. Your ClinCard payment information will not be shared with any third parties and will be kept completely confidential

This information will remain confidential unless you give your permission to share it with others, or if we are required by law to release it.

UT Southwestern, as a State agency, will not be able to make any payments to you for your participation in this research if the State Comptroller has issued a “hold” on all State payments to you. Such a “hold” could result from your failure to make child support payments or pay student loans, etc. If this happens, UT Southwestern will be able to pay you for your taking part in this research 1) after you have made the outstanding payments and 2) the State Comptroller has issued a release of the “hold.”

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for

this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or Children's Medical Center.

You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.
If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

Your doctor is a research investigator in this study. She is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or becomes worse.
- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my information be kept confidential?
Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Children's Medical Center; and
- The UT Southwestern Institutional Review Board.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Whom do I call if I have questions or problems?
For questions about the study, contact Dr. Zia at (214) 456-2382 during regular business hours, and at (214) 456-7000 after hours and on weekends and holidays and ask the operator to page the hematologist on call.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.

_____

Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Legally Authorized Representative's Name (Printed)

_____ _____ _____ AM / PM

Legally Authorized Representative's Signature Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time

ASSENT OF A MINOR:

I have discussed this research study with my parent or legal guardian and the researchers, and I agree to participate.

_____	_____	_____ AM / PM
Participant's Signature (age 10 through 17)	Date	Time

Interpreter Statement:

I have interpreted this consent form into a language understandable to the participant and the participant has agreed to participate as indicated by their signature on the associated short form.

_____
Name of Interpreter (Printed)

_____	_____	_____ AM / PM
Signature of Interpreter	Date	Time

Witness [Needed when the interpreter is not physically present, i.e. a language line is used]:

I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legal authorized representative.

_____	_____	_____AM / PM
Name of Witness (Printed)	Date	Time
_____	_____	_____AM / PM
Signature of Witness	Date	Time