Consent and Authorization to participate as a Research Subject in:
Flares of Low Back Pain with Activity Research Study ("FLAReS")

SUMMARY OF STUDY: This study observes people with low back pain over a 1-year period to determine how physical activities and other things that people do may affect their low back pain. The study will not change the medical care you receive. Your care providers (doctors and nurses) will not know you are in the study nor be able to see any of your study information.

We are inviting you to be in a research study. The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully.

You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

Principal Investigator:
Pradeep Suri, MD, MS
[redacted]

Research Staff:
Adrienne Tanus, MPH
Bianca Irimia, MPH
John Phillips
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Study Title:
Effects of Physical Activities on Pain and Functional Recovery in Low Back Pain

Study Phone:
[redacted]

1. Who can I contact with questions while I am in this study?

During business hours (6:30 a.m. – 3:30 p.m.), please call research staff or the principal investigator at the numbers listed above. After business hours (nights and weekends), please call the study staff phone number listed above and leave a voicemail with your name, phone number, and the best time to reach you. Study staff will call you back the following business day.

The study researcher(s) listed above must be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues specifically related to the study.

You may also contact the Institutional Review Board (IRB) at [redacted] if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

2. What is the purpose of this research study?

We are inviting you to participate in this research study because you have low back pain. Past research has shown that physical activities may have either beneficial or harmful effects on low back pain.

"Flares" of low back pain are periods of time when your pain becomes distinctly worse. Flares are sometimes thought to be triggered by the short-term effects of physical activities that might harm the back, such as heavy lifting. Other types of physical activities, like stretching, may decrease the chances that you have a flare of pain. On the other hand, some types of activities, such as walking or doing low-impact aerobic exercises, are thought to have long-term beneficial effects on low back pain.

Past research has done little to distinguish the specific types of activities that may affect low back pain in day-to-day activities or to distinguish the short-term effects of specific physical activities (lasting hours to days) from the long-term effects of physical activities (lasting weeks to months or longer).

The purposes of this research are to answer the following:

- In the short term (hours to days), which specific physical activity types make low back pain worse? Or better?
- In the long term (over many months), which specific physical activity types make low back pain worse? Or better?

Answering these questions will allow doctors and nurses to provide patients who have low back pain specific recommendations about which physical activities are recommended and which would best be avoided.

We are planning to enroll 550 patients for this study from VA Puget Sound. Participants must be 18-65 years old, have low back pain, and be able to complete the data collection processes that the study involves.

Participants will be in the study for 1 year. There are no visits associated with the study. However, participants would complete many short electronic surveys (e-Surveys) using their own personal electronic devices (personal computer [PC], tablet, or smartphone) over the course of the study. Each e-Survey will take between 10 and 40 minutes to complete.

3. What will I be asked to do in this research study?

Participating in this study involves completing e-Surveys over a 1-year period and you may be asked to wear an ActiGraph unit for 4 weeks. There are no treatments that you would receive as part of this study. If you decide to participate, your normal medical care would not change in any way. Your clinical providers (doctors and nurses) will not be able to see the results of any information you provide during the study, and no documentation in your medical record will be made if you participate in the study.

Screening. We will determine if you are eligible for the study during in-person conversations while you are at the VA or over the phone. This may include the discussion you are having right now.

ActiGraph. You may be asked to wear an ActiGraph for this study. The purpose of wearing the ActiGraph for 4 weeks is to closely track your physical activity and sleep, such as the number of steps and the frequency of when you walk each day, the times you are sitting, and the times you are sleeping. The ActiGraph is a small device that is about the size of a large wristwatch.

If you are asked to wear an ActiGraph, we will ask you to wear the ActiGraph daily when you are not in water (for example, while showering or swimming). You will need to wear the ActiGraph when you are resting, walking around, and sleeping. When you are awake, we ask you to wear the ActiGraph on one of your thighs using the thigh strap that we will provide to you. At the end of the 4-week period, we will ask you to send the ActiGraph back to us using a postage-paid envelope that we will provide to you.

Medical record information. While you are in this study, we will need to look up past and future information in your medical record (up to 2 years from the time you start this study). We will use this information to know about your low back pain history and your other medical history so it can be accounted for in the analyses we conduct. We will only use administrative data from your medical record (like billing codes or procedure codes). We will not share this information outside the VA as part of the study.

Joint enrollment in a VA research study and a University of Washington (UW) research study

In this document, the information we provide about the UW research processes is in dark gray and a different font so you can easily tell which parts of the research involve UW. Participants in this VA study will also be expected to enroll in a component of the research conducted at the UW. The UW component will involve a process of receiving information and deciding whether you want to participate in research ("informed consent"); that is separate from the informed consent session you are participating in right now. **You are not consenting to the UW research processes by completing this informed consent session and signing this form.** However, we are providing you with some basic information about what the UW component will involve so you are not surprised when you receive this information later. More detail about the UW component of the research is provided in the "Summary of UW Research Processes" document that is provided to you separately.

The primary activity involved in the UW component of this research is completing e-Surveys. The e-Surveys are conducted by the DatStat company, a private (non-VA) company specializing in administering secure HIPAA- and 21 CFR 11-compliant electronic questionnaires, through research processes at the UW.

Baseline e-Survey. After this informed consent session, if you decide to participate in this study, you will need to go to the FLAReS Participant Portal at [redacted] within 24 hours to register in the UW

research processes. There you will receive information about the e-Surveys that constitute the UW research processes, similar to the information you are being provided with now. If you decide to participate in the UW research processes, you will be offered an electronic informed consent (e-Consent). If you complete the e-Consent, you will be offered to complete a Baseline e-Survey. The Baseline e-Survey will take 30-40 minutes to complete.

Scheduled e-Surveys. Following the Baseline e-Survey, Scheduled e-Surveys will take place *many times over the 1-year period*. They will occur at the following frequencies:

Weeks 1-4 after this session:	Three e-Surveys each week
Weeks 5-8 after this session:	One e-Survey each week
Months 2-12 after this session:	Two e-Surveys each month

Each Scheduled e-Survey will take 10-25 minutes to complete. The possible total you will need to complete is 36 Scheduled e-Surveys over the 1-year study period. You will receive electronic notifications called "e-Alerts" by text message and/or email during certain times of day when it is time for you to complete a Scheduled e-Survey. You will choose in advance the *general* times of day when you may receive an e-Alert to complete a Scheduled e-Survey, but the *exact* time of day when e-Alerts are sent will be varied, as will the days on which e-Alerts are sent. This means that you will not know in advance exactly when an e-Alert is coming. If you do not complete a Scheduled e-Survey on a given day, these e-Alerts will be repeated hourly up to three times to remind you about the e-Survey.

Flare Window e-Surveys. As described above, "flares" of low back pain are periods of time when your low back pain becomes distinctly worse than it has been recently. We will also ask you to complete Flare Window e-Surveys within 3 hours of the time your flare begins (if possible) whenever you are experiencing a flare of your low back pain. Each Flare Window e-Survey will take 10-25 minutes to complete. Flare Window e-Surveys can be completed at any time by going to the FLAReS Participant Portal at [redacted] and clicking on the link marked "Enter a Flare Window e-Survey."

Exit e-Survey. At the end of the 1-year study period, you will complete an Exit Survey. It will take 25-35 minutes to complete.

Two examples of the most personal or sensitive questions that you will be asked during your participation in this study are as follows:

Example 1:

Using the scale below, please indicate how often you have been engaging in this thought or activity when you have been feeling pain over the past 24 hours?

"When I feel back pain, I think it's terrible and I feel it is never going to get any better."

•	•	•	•	•	•	•
0	1	2	3	4	5	6
I never do that			I sometimes do that			I always do that

Example 2:

"Stress" means a state in which a person feels tense, restless, nervous, or anxious or is unable to sleep at night because his/her mind is troubled all the time. Have you felt this kind of stress over the past 24 hours?

•	•	•	•	•
0	1	2	3	4
Not at all	Just a little	To some degree	Quite a bit	Very much

4. What are some risks of joining this research study?

Participating in the study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. If any of the risks included in this Consent Form become significantly updated during this study, we may ask you to sign an updated Consent Form to document that this new information has been explained to you. You will have the right to decide either to continue with the research study or to withdraw.

Below are study-related risks that are known at this time:

Physical risks. You may find it uncomfortable or inconvenient in general to wear the ActiGraph during the day and/or while sleeping, if asked to wear the device. There is no risk of electrical shock while wearing the activity monitor and it cannot track where you are. You may experience sweating or skin irritation while wearing the activity monitor if you have sensitive skin.

Boredom, inconvenience, frustration, stress. You may feel fatigue and/or boredom when completing e-Surveys. Some people may find some of the questions we ask during the telephone interviews and online surveys personal or sensitive, which may cause mild stress or discomfort. Some questions may cause you to focus your attention on pain and, as a result, lead to a temporary increase in pain intensity. You may experience mild frustration, stress, and/or annoyance while reporting on pain and mood on the e-Surveys or from receiving e-Alerts as notifications to complete e-Surveys.

Privacy and confidentiality. There is a possible risk of loss of privacy with participation in this study. Information that identifies you will be used in this study and shared with research staff. Although the research team will make every effort to protect your private health information and guard against any loss of privacy, accidental breaches in confidentiality do sometimes occur.

Although extremely unlikely to occur, a breach in confidentiality and a resulting loss of privacy could have significant effects (such as monetary loss due to identity theft, legal problems, some type of discrimination resulting in loss of health and/or life insurance coverage, or loss of job).

If you believe that any of the possible risks above have affected you during the study, please contact the VA research staff by phone as listed on page 1.

There is also a possible risk of loss of privacy involving the UW component of this study. We encourage you to review the "Summary of UW Research Processes" document, which will provide you with more information about these possible risks.

5. What are some benefits of joining this research study?

Participation in this study will not provide you with any direct benefits. The researchers expect the information gathered during the study will help them to better understand and design treatment for individuals with low back pain in the future.

6. Are there other ways I could receive these benefits?

This study is voluntary and for research purposes only. The alternative to the study is to not take part in it.

7. Who will see my information and where will it be stored?

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study. These aspects are described further below in Section 11. If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

Study code and link

Your privacy is important to us. We will not place your name on any research data. Instead, we will assign a study code whenever possible to identify your information, such as your survey responses.

We will keep a master list that links your name to your study code in a secure-access computer specifically for research data. The master list will be stored in a separate password-protected folder and will only be accessed by the authorized study staff members.

Storage for safekeeping

Part of your research records will be stored in paper form in a locked file cabinet (in the locked office space of the Seattle ERIC at VA Puget Sound) and part will be stored electronically. The file cabinets and computers will be locked and are housed in rooms that are locked when unoccupied. Electronic data will be stored in encrypted, password-protected files on the VA secure research server with access restricted to VA research staff on this study team. Data will not be stored on any laptops or computers outside VA Puget Sound.

Data stored at DatStat and at the UW

As you complete e-Surveys, data will be automatically generated. These data are encrypted while at rest on your personal electronic device and secured in transit with SSL (Secure Sockets Layer) technology, a standard security technology for establishing encrypted links between your device and the DatStat server. The data are encrypted and stored on a secure server operated by DatStat and in a secure electronic database maintained by researchers at UW. Our VA research study team will obtain your data from DatStat, after which time it will be stored in a secure VA database with access restricted to VA research staff on this study team as described above under "storage for safekeeping." After VA researchers obtain your e-Survey data for the 1-year study period, DatStat will delete all your data. Researchers at UW will retain a copy of your data which will not include any information that could link you to your data. Further information about data storage at DatStat and at UW will be provided to you when you complete the informed consent process at UW.

After study completion

Once this study is completed, we will not use the study code linking you to your data for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data indefinitely.

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing. Neither you nor your family will gain financially from discoveries made in the future using the information you provide.

8. What are some other things to think about before I decide to join this research study?

The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

Possible usage costs associated with the UW research procedures

You may incur costs associated with receiving e-Alerts via text messages and/or the usage of internet data required to complete the e-Surveys. Please check your mobile phone text and/or data plans to determine if this will affect you. We will not reimburse you for any messaging or data charges incurred as part of participation in this study.

We will compensate you for the following study-related procedures:

Study Procedures	Each	Total
Informed Consent	$20	$ 20
Baseline e-Survey	$12	$ 12
Scheduled e-Surveys (up to 36)	$7	$ 252
Flare Window e-Surveys (e-Surveys 1-10)	$7	$ 70
Flare Window e-Surveys (e-Surveys 11-20)	$4	$ 40
Flare Window e-Surveys (e-Surveys 21-30)*	$2	$ 20
Exit e-Survey	$15	$ 15
Mail return of the ActiGraph in pre-paid packaging (if using device)	$30	$ 30
Total possible compensation (without ActiGraph)		**$429**
Total possible compensation (with ActiGraph)		**$459**

*We will not compensate you for Flare Window e-Surveys that you complete beyond the first 30.

In sum, if your study participation involves wearing the ActiGraph unit, we will compensate you up to $459 if you complete all VA research-related study processes over 1 year and return the ActiGraph unit. If you are not asked to wear an ActiGraph device, we will compensate you up to $429. Payments will be made by check from the US Treasury and are usually labeled as a "miscellaneous payment" without mentioning any other specifics such as this study or VA. Payments will be bundled together into three checks to minimize inconvenience. This includes a first payment issued 2 months after you join the study, a second payment issued 7 months after you join the study, and a third payment issued 1 year after you join the study. Payments may take up to 5 months to reach you after the time the study issues them. To comply with Internal Revenue Service (IRS) guidelines, we will collect your social security number. You may receive an IRS Form 1099.

9. What will happen if I decide I don't want to be in this research study later?

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

We may withdraw you from the study without your consent if we feel you are not able to fulfill the study requirements, such as not completing a sufficient proportion of e-Surveys or questions within e-Surveys during the study, or not wearing your ActiGraph during the 2-week run-in period, if asked to wear the device. Additionally, you may be withdrawn if you become incarcerated during the course of the study or if there is reason to believe study participation may cause an unanticipated safety risk to you or the study staff.

If you decide to withdraw from the study, no new information will be collected from you. Information already collected up to that point will continue to be used for the study. If you would like to withdraw your permission for us to access your electronic medical record for research purposes, please call the research staff at the numbers provided on page 1 of this document.

10. What will happen if I am hurt in this research study?

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act. You do not waive any legal rights by signing this Consent Form.

11. Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal laws, state laws, and the federal medical law known as the HIPAA Privacy Rule also protect your privacy. By signing this Consent Form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this Consent Form. They may also collect other information including your name, address, date of birth, and information from your medical record such as administrative diagnostic codes related to your medical and mental health treatment.

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study. If we learn you intend to harm yourself or others, we must report this information to appropriate authorities. The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members at the VA
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research

- The VA Puget Sound Fiscal Department and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

Your health information disclosed pursuant to this authorization may no longer be protected by federal laws or regulations and may be subject to re-disclosure by the recipient.
You can revoke this authorization in writing at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Pradeep Suri and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on your signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

12. What am I agreeing to by signing this form?

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are available to me.

My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this Consent Form.

I agree to participate in this research study as described in this document.

_____ _____

Subject Signature Date

_____

Print Name of Subject