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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Pilot Study of Personalized Patient Education for Chronic Low Back Pain

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Why is the research being done?

Chronic low back pain (LBP) is a condition with high prevalence and significant impact on health systems worldwide. Notably, LBP is recognized as the primary cause of disability across the globe, contributing to 65 million years lived with disability (YLDs) in 2019. Rehabilitation is instrumental in assisting patients to comprehend their pain, return to enjoyable activities, and find strategies for recovery and improved functionality. However, there are notable disparities in LBP-related disability, with significant differences observed in treatment and rehabilitation use based on socioeconomic status.

Patient education is a cornerstone of effective patient care. However, there is a lack of guiding evidence for educational interventions aimed at reducing disparities in LBP management during rehabilitation. Within the UPMC health system, there are no standardized patient education materials provided to individuals who present to a physician or rehabilitation clinic with chronic LBP.

The overall goal of this project is to obtain preliminary data for a future grant application that will

utilize informatics and telehealth technologies to address these challenges, making the provision of tailored patient education materials for LBP patients more feasible and ultimately reducing disparities. In this pilot study, we will examine the use of customized educational materials for patients with chronic LBP and examine their impact on participant LBP-related self-efficacy and patient-reported functional outcomes.

The overall goal of the SmartBack project is to develop technology to provide personalized patient education for patients with chronic LBP. This preliminary study will help provide necessary support for a future grant application to support development and initial testing of the SmartBack application.

In this preliminary study, we aim to establish the potential utility of personalized patient education materials for patients with chronic LBP to improve disease-specific self-efficacy and patient-reported functional status.

Who is being asked to take part in this research study?
You are being asked to participate in this study because you have had chronic low back pain for longer than 12 weeks and have sought care for LBP within the past 12 months. You're older than 18 years old and live in Pittsburgh. You also have not had any prior spine surgery, any orthopedic surgery in the past 6 months. You must also have access to high-speed internet and/or LTE wireless service and be able to access your email on a tablet, phone, and/or laptop. We anticipate that approximately 30 people with LBP will be recruited to participate in the study.

What procedures will be performed for research purposes?
If you decide to take part in this research study, your participation will last approximately 3 weeks and you will undergo the following procedures:

Day 0
You will be emailed a group of questionnaires to complete regarding demographics and clinical questions.

Day 5
You will be emailed a basic low back pain education program to follow.

Day 8
You will be emailed a second basic low back pain education program to follow.

Day 11
You will be emailed a third basic low back pain education program to follow.

Day 14
You will be emailed a fourth basic low back pain education program to follow.

Day 17
You will be emailed a fifth basic low back pain education program to follow.

Day 21
You will be emailed follow-up questionnaires and surveys.

We are also requesting your authorization or permission to review your medical records to determine confirm that you meet the conditions for participation in this study. We will obtain the following information: heath care visits information withing the past 12 months for low back pain. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. Your medical information as well as information

obtained during your research study may be shared with other groups possibly including authorized officiations from the University of Pittsburgh Office of Research Protections for the purpose of monitoring the study. We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University of Pittsburgh. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any inforatmion obtained from you up to that point will continue to be used by the research team.

What are the possible risks, side effects, and discomforts of this research study?
Completing questionnaires comes with an infrequent risk of a confidentiality breach and anxiety or nervousness. In addition, there is a risk of a confidentiality breach associated with consenting to the research team accessing your outpatient physical therapy records. Should you experience anxiety or nervousness, you will be permitted to take a break, skip a question or stop your participation. The information we collect will be written on a form that does not include your name, date of birth, or other identifiable information—we will use a unique code to identify you, and no one outside the research staff will be able to link the code to your name. As with all research data, your information will be stored in a locked file cabinet, and only research team members will have access.

What are the possible benefits from taking part in this research study?
It is possible that you will benefit from this study by learning more information about living with chronic low back pain and what professional guidelines recommend in terms of treatment for chronic low back pain.

Will I be paid if I take part in this research study?

If you participate in all elements of this study, you will be paid a maximum of $100, split as follows: $25 for completion of all baseline questionnaires; $25 for completion of all follow-up questionnaires; $5 for each of the 5 days that you access the patient education materials you receive from the study team; and a bonus of $25 if you access all 5 days of patient education materials.

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a “Form 1099 – Miscellaneous” with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for ‘backup withholding;’ thus you would only receive 76% of the expected payment.

Who will know about my participation in this research study?
To ensure that the confidentiality of any information obtained about you from this research study is maintained, records associated with your participation in this study will be indicated by a case number. Information linking these case numbers with subject identity will be accessible only to the investigators and their research team and will be stored in a locked file. In addition, the information linking your case number to your identify will be stored separately from research data. You will not be identified by name in any publication of research results.

Any data that includes your identity will be stored in locked files at all times. In the research

database, a number will be assigned to your information, and your name will not be included in the database. Also, the research database will not be accessible without a password to the research staff and will not be shared with anyone who is not directly associated with this research project. In addition, your identity will not be revealed in any description or publications from this research.

Will research data be placed in the medical record?
Information about participating in this study will **not** be placed into any other medical records held at UPMC Hospitals or the University of Pittsburgh. Any additional information we obtain from you will NOT be placed into your medical records at UPMC or any other place where you may have received care.

Who (other than the investigators) will have access to identifiable information related to my participation in this research study, and how will they use it?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study: Authorized representatives of the University of Pittsburgh Office of Research Protections, and the Department of Physical Therapy, may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

How long will this information be made available to the researchers?
The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for an indefinite period of time. It is a University policy that all research records must be maintained for at least 7 years following study completion. De-identified data may be shared with investigators with similar interests in the future.

What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study?
Upon learning of a clinically significant, unexpected disease or condition, the study team member who makes the discovery will immediately notify the PI (Bove). You will be referred to appropriate clinical care if needed. Dr. Bove will work with you and the study team to preliminarily evaluate the seriousness of the event and whether it may be study-related. Dr. Bove will ensure notification of the IRB within 24 hours of the study team learning of any serious or study-related adverse event. In cases where the study team is unable to determine whether the event is study-related or serious, Dr. Bove will also notify the IRB within 24 hours and seek assistance.

Is my participation in this research study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC Health System hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your physician and/or physical therapist may be involved as an investigator in this research study. As both your physician/physical therapist and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another physical therapist or physician who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician or physical therapist.

If I agree to participate in this research study, can I be removed from the study without my consent? The investigators may withdraw your participation if you are unable to complete all of the testing procedures related to this study. Any identifiable research or medical information recorded for, or resulting from your participation in this research study prior to the date that you are withdrawn from participation may continue to be used and disclosed by the investigators for the purposes described.

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VOLUNTARY CONSENT
The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified member of the research team or by Dr. Bove (412.624.9255). I understand that I may always request that my questions, concerns or complaints be addressed to Dr. Bove. At any time I may also contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1.866.212.2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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 this website at any time.

By signing this form, I agree to participate in this research study, and authorize the use and disclosure of my medical record information for the purposes described above. A copy of this

consent form will be given to me.

_____ _____

Participant's Signature Date

_____

Participant's Printed Name

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date