**Official Title:** Implementation of the ACP Guideline for Low Back Pain (IMPACt-LBP)

**NCT:** NCT05626049

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**Informed Consent Form and**
**Authorization to Use and Disclose Protected Health Information**

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| **Sponsor / Study Title:** | **Duke University / "Implementation of the American College of Physicians Guideline for Low Back Pain: A Cluster Randomized Trial(IMPACt-LBP)"** |
| **Principal Investigator:** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

SUMMARY OF KEY POINTS:

1. *You are being asked to read this consent form so you can make a decision about joining or not joining a research study. Your participation is voluntary.*
2. *The purpose of the research is to help doctors understand how patients with low back pain respond to receiving care from different health care providers such as primary care providers, chiropractors and/or physical therapists.*
3. *There may be no benefit to you for being in this study; we hope your participation in the study will help others like you with low back pain in the future.*
4. *You will receive care for your low back pain even if you choose not to take part in this study.*
5. *After you read this consent form you will be given a questionnaire. If you complete the first questionnaire, that will indicate you want to participate in this research study. Some of the questions you will answer refer to your symptoms, pain, and treatment/health care services received and those may make you feel uncomfortable. However, these will help your providers treat you. There is potential risk of loss of confidentiality of your answers.*

***You are being asked to take part in a research study.***

You are being asked to take part in this research study because you have low back pain and your primary care clinic is part of a national research study being carried out at Duke, Dartmouth-Hitchcock, and the University of Iowa. The study purpose is to assess how subjects with low back pain respond to receiving care from different types of providers, such as primary care providers, chiropractors, and physical therapists. The study does NOT involve any experimental treatments. Your specific treatments will be decided by you and your provider(s). Some clinics were chosen, by chance, to offer subjects with low back pain an initial visit with either a physical therapist or chiropractor, while other clinics will continue to provide care as usual.

As part of this study, you will complete short questionnaires about your back pain, physical activity and treatments/health care services received. These questionnaires should take about 5-10 minutes to answer and after completing this first one, other questionnaires will be sent to you in 1, 3, 6, 12, and potentially at 24 months if the study has not ended before then. We plan to enroll about 1800 people from approximately 26 primary care clinics within 3 major healthcare systems in this study. By joining this study and completing the questionnaires, you will help provide valuable information on how to better care for people like you with low back pain.

Your involvement in the study is voluntary. You do not have to participate if you do not want to and you can leave the study at any time without penalty or loss of benefits. You will receive the same care whether you fill out the questionnaires or not.

You may or may not get benefit from participating in this study, but there are no physical risks associated with this study. No long-term medical care or financial compensation for research-related injuries will be provided by the Sponsor (Duke University), the NIH or the Federal Government.

You may get bored or frustrated answering the questionnaires. There may be risks that are unknown.

You will be asked if you want to provide a personal email address and phone number where study specific questionnaires will be sent so you may complete the questionnaires online at the required time points. If you provide your email address and phone number this information may be seen by entities outside your study site. Your email address will only be utilized for transmitting information to you so you may complete study related questionnaires. If you provide your phone number it will be used by a web-based system, called Twilio, for sending you reminders about the questionnaires. You will not be able to contact study team members by responding to these emails or texts. If you chose to provide an email address or phone number there is the possibility you may be able to be identified outside <Your institution>. As long as you agree and are a member of the study, we will contact you this way when it is time to complete your questionnaires and then at 24 months if the study has not ended by then. You may receive up to 3 reminders each time if the questionnaires are not completed. In addition, the Scheduling Assistant may reach out to you to ask if you need any help completing the questionnaires. If you change your mind about how you would like to receive the emails or messages or if your contact information changes, please contact the study team. You have the option to participate in this study without providing your email address and phone number.

If you do not wish to participate, please indicate that on the first questionnaire. You are free to skip any questions you would prefer not to answer; however, for the initial questionnaire we may contact you to verify you intentionally skipped the question. If you do not complete the 2 initial PROMIS questionnaires, you will not be enrolled in the study. If you agree to participate now and change your mind later, you can choose not to complete future questionnaires. Your decision to participate in this study or not will not affect your treatment or be held against you in any way.

The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name.

This study is for research purposes only. The only alternative is to not participate in this study.

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

To conduct this study, researchers need to use your health care information. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (Health Insurance Portability and Accountability Act [HIPAA]). For this study, we will be looking to see what specific treatments you received for your back pain and what the results of those treatments were, as well as any problems that may have occurred as a result of those treatments.

If you decide to be in this study, the Investigator and research team will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Email address.
- Date of birth.
- Dates of service for medical visits and treatments
- Medical history.
- Information from your study visits, including all test results.

Federal law provides additional protections of your medical records and related health information. By completing the first questionnaire, you allow the research team to use your health information and give it to others involved in the research. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of Duke University.
- Representatives of Duke Clinical Research Institute.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To compare a Primary Spine Practitioner model of care to other forms of treatment of low back pain.
- For other research activities related to a Primary Spine Practitioner care for low back pain.

There are protections in place to keep your PHI and research data confidential. Data for this study will be stored and analyzed using a code rather than personal identifying information. We will keep a separate file containing the linkage between the code and your personal information on a secure password protected server accessible only to the research team. Once the study is

complete, we will destroy the file containing the link between your identifying data and the code. You may withdraw your permission for us to use your health information for this research study by sending a written notice to the Investigator at the address listed on the first page of this form. However, we may still use the information collected before you withdrew. Once we have removed your identifying information, it may not be possible to prevent its future use.

There is no intention to disclose your PHI to others outside of the study. However, HIPAA requires notification so you are aware that if your PHI is disclosed to others, federal privacy laws may no longer protect it.

Your permission to use your health information for this study will not end until the study is completed. In California and any other state that requires an expiration date, the Authorization will expire in 50 years.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data. You have a right to receive a copy of the information in your medical record at any time.

The researchers may write papers and make presentations about this study. Your name or information that might identify you will not be used in these papers or presentations. Identifiable data collected for this study will be used only for research purposes that are determined to be reasonable by a review committee. Once data collected for this research study is no longer identifiable, the data could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

A description of this clinical trial will be available on **http://www.ClinicalTrials.gov**, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**COMPENSATION**
«Compensation»

If you do choose to complete the questionnaires, you will receive $20 for questionnaires completed at each time point up to a maximum of $120 total for the entire study period. To receive this payment, you may need to provide your name and social security number to an office at **(Local Site Name)** that distributes these payments. You do not need to provide this information or receive these payments in order to participate in this study.

There will be no charge to you for your participation in this study. You or your insurance provider will be responsible and billed for all costs related to any medical care you receive, including copayments and deductibles. There may be additional costs to you as a result of being in this research study including time, travel, and phone/data/text message costs.

**CERTIFICATE OF CONFIDENTIALITY**
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires

disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

**WHOM TO CONTACT ABOUT THIS STUDY**

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

**Please contact the Investigator at the telephone number listed on the first page of this consent document.**

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00061074.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

You do not have to complete this first questionnaire; it is completely voluntary. If you do complete the questionnaire, you acknowledge the information provided above and your agreement to participate in the study.