**Informed Consent Form**

Parker University

Title of Project:

# Principal Investigator:

**Co-Investigators:**

**Coordinators:**



**Participant’s Printed Name:**

**INTRODUCTION**

We invite you to take part in a research study at Parker University, which seeks to OBJECTIVE OF STUDY .

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members. If you decide to participate, you must sign this form to show that you want to take part.

# Section 1. PURPOSE OF THE RESEARCH

You are being offered the opportunity to take part in this study because you are a student in Parker’s University doctor of chiropractic program. This research study is being done to OBJECTIVE OF STUDY . This information will also be used to collect information for future research studies on this topic. Approximately

\_NUMBER\_ people will take part in this research study.

# Section 2. PROCEDURES

If you decide to participate in this research study, you will have discussed the study reason and procedures with study personnel and had the study procedures demonstrated for you. If you are interested in participating and have signed this consent document, you will then LIST STUDY PROCEDURES .

# Section 3. TIME DURATION OF PROCEDURES AND STUDY

If you agree to take part in this study your involvement will last approximately

 DAYS/ HOURS/ MINUTES . The time requirement for this study includes:

* Test Day #1: IF APPLICABLE \_
* Test Day #2: IF APPLICABLE \_

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# Section 4. DISCOMFORTS AND RISKS

While on the study, you are at risk for the following side effects. Most of them are listed below but they will vary from person to person.

# Chiropractic Treatment

* + **More likely:** Some patients will feel stiffness or soreness following the first few days of treatment.
	+ **Less likely:** Fracture.

All side effects identified in study will be followed up with according to the Parker Chiropractic Wellness Clinic standard protocol and procedures, as well as documented in the study records for reporting in the final manuscript.

# Section 5. POTENTIAL BENEFITS

The results of this research study may guide the future research studies of balance after chiropractic adjustments.

# Section 6. STATEMENT OF CONFIDENTIALITY

* 1. **Privacy and Confidentiality Measures**

Your research records that are reviewed, stored, and analyzed at Parker University will be kept in a secured area in the Research Center. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

# The Use of Private Health Information

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law, as explained in the Parker University Privacy Notice. If you have not received this notice, please request a copy from the study coordinator. At Parker University your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people or groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the study team to use your health information. If you do not want us to use your protected health information, you may not participate in this study.

Your permission for the use, retention, and sharing of your identifiable health information will expire upon completion of the research study. At that time the research information not already in your health record will be destroyed. Any research information in your health record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your information at any time. You must do this in writing. Write to

 NAME OF INVESTIGATOR and let him know that you are withdrawing from the research study. Her mailing address is:

2540 Walnut Hill Lane Dallas, TX 75229

If you withdraw your permission:

* We will no longer use or share health information about you for this research study, except when the law allows us to do so;
* We are unable to take back anything we have already done or any information we have already shared with your permission;
* We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research;
* We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information:

* Health information collected during your screening interview and test days.
* The information collected is only during the time span of the research study.

Representatives of the following people or groups within Parker University may use your health information and share it with other specific groups in connection with this research study.

* The investigators identified above
* The Parker University Institutional Review Board
* The Parker University Human Subjects Protection Officer
* Co-Investigators affiliated with this study at Parker University who might need to use and/or disclose the participant’s information in connection with this study.

The above people or groups may share your health information with the following people or groups outside Parker University for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original Parker University records.

* The Office of Human Research Protections in the U. S. Department of Health and Human Services
* Consultants for the study LIST EXTERNAL COLLABORATORS

# Section 7. COSTS FOR PARTICIPATION

Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance, and/or co-pay.

You will not lose any legal rights by signing this form.

# Section 8. COMPENSATION FOR PARTICIPATION

All treatment provided in relation to this study will be provided at no cost. Care beyond this study will not be provided. Snacks will be available for participants on both test days for no cost.

# Section 9. RESEARCH FUNDING

All study costs are covered by the internal budget from Parker University’s Research Center.

# Section 10. VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include doing the screening interview and completing the test day procedures. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

# Section 11. CONTACT INFORMATION FOR QUESTIONS OR CONCERNS

You have the right to ask any questions you may have about this research. If you have questions, complaints, or concerns or believe you may have developed an injury related to this research, contact NAME OF INVESTIGATOR at

 PHONE NUMBER .

If you have questions regarding your rights as a research participant or you have concerns or general questions about the research or about your privacy and the use of your personal health information, contact the research subjects protection advocate in Parker University at (972) 438-6932 x7321. You may also call this number if you cannot reach the research team or wish to talk to someone else.

For more information about participation in a research study and about your institutional review board (IRB), a group of people who review the research to protect your rights, please visit the Parker University IRB’s Web site at TBD. Included on this Web site, under the heading “Participant Information,” you can access Federal regulations and information about the protection of human research participants. If you do not have access to the Internet, copies of these Federal regulations are available by calling the Parker’s University IRB at (972) 438-6932 x7321.

**SIGNATURE AND CONSENT/PERMISSION TO BE IN THE RESEARCH**

Before making the decision regarding enrollment in this research, you should have:

* Discussed this study with an investigator;
* Reviewed the information in this form; and
* Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research, and have received answers to those questions. You will receive a copy of the signed and dated form to keep for future reference.

 **Participant:** By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

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|  \_ |   |   |
| Signature of Participant Date | Time | Printed Name |

**Participant’s Legally Authorized Representative:** By signing below, you indicate that you give permission for the participant to take part in this research.

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| --- | --- | --- | --- |
|  \_ |   |   |   |
| Signature of Participant’s | Date | Time | Printed Name |
| Legally Authorized |  |  |  |
| Representative |  |  |  |

The signature of the participant’s legally authorized representative is required for people unable to give consent for themselves.

Description of the Legally Authorized Representative’s Authority to Act for Participant

**Person Explaining the Research:** Your signature below means that you have explained the research to the participant or participant representative and have answered any questions about the research.

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| Signature of Person | Date | Time | Printed Name |
| explained this research |  |  |  |