

MIST2 Consent

Please review the informed consent information below.

If you are consenting on behalf of a son/daughter / other, the terms 'you' and 'your' should be read as your 'son/daughter/other'.

1.) What is the purpose of this study?

This is a research study being conducted with consultation from a scientist at the University of Alberta. You are being asked to participate because you are seeking chiropractic care at the Parker University's Teaching Clinics.

The purpose of the study is to collect information related to patient's experience of spinal manipulation therapy (aka adjustments), including safety information. This information will be used to assess the feasibility of conducting research at the Parker University Clinics, test the feasibility to use electronic surveys, and to better design future studies on this topic. In addition, it will also support patient safety by helping clinicians and student interns to be proactive in identifying safety concerns that their patients may identify through this study.

Before you make a decision regarding your participation, a study coordinator will explain the study and what will be asked of you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be offered a copy of this information for your records.

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care you are provided here.

2.) What will happen and how long will you be in the study?

For this study, you will be asked to complete 2 surveys.

The first will be completed before your treatment using this iPad.

The second survey will be sent to you via email 2 days after your appointment. This survey is requested to be completed within one week of your appointment.

Each survey will take approximately 1-5 minutes to complete. If you need to provide a lot of information, there is a chance that they may take 10 minutes to complete.

All individual information is confidential with access only to study investigators, all others will only see results of all participants together. However, there are some items that we may ask you if we can share your findings with your intern to obtain more information. You have the right to say 'yes' or 'no' without any effect on your study participation or clinic visits.

3.) Costs to you if you take part in this study:

There is no cost to you for taking part in this study. Please note, you are still responsible for paying for the care you will receive.

4.) Side effects and risks that you can expect if you take part in this study:

There are no known risks associated with participating in this study; however, it is not possible to know all of the risks that may happen in a study.

Some of the questions may be sensitive in nature and bring up uncomfortable feelings. Please know that you can stop the survey at anytime.

There are some questions that we may ask you if we can share your findings with your intern to obtain more information. You have the right to say 'yes' or 'no' without any effect on your study participation or clinic visits.

Additional Information:

5.) Good effects that might result from this study is your benefit to science and humankind that might result from this study:

6.) There is no compensation for your time to take these study surveys.

7.) Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact:

Dr. Katherine Pohlman at 972-438-6932 ext. 7148 or

Dr. Patrick Bodnar (clinic director) at 972-438-6932 ext. 7525.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call Parker University's Institutional Review Board Office at 972-438-6932 ext. 7321.

Information on Confidentiality, Authorization to Use/Disclose Protected Health Information, and Agreement to Participate in Study.

8.) Confidentiality:

During the study, if you choose to complete the surveys, we will collect data about the care you received at the Parker University's Teaching Clinic. We will do everything we can to make sure that this data is kept private. Sometimes, by law, we may have to release our data and the information you provided, so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private. All electronic data will be kept on the secure REDCap database with designated, restricted access to only necessary personnel.

Proceed to review of confidentiality, use/disclosure of protected health information authorization and agreement to participate in study?

Yes No

Thank you for your interest in this study. Please return the iPad to the study coordinator or your intern.

9.) Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Parker University as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, the study team may share the results of your study, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and Parker University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept for at least six years after the study is finished.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Katherine Pohlman in writing and let her know that you withdraw your consent. Her mailing address is 2540 Walnut Hill Lane, Dallas, TX 75229. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality, unless otherwise stated by you in your withdrawal.

If you decide not to take part in this research study, it will not affect your treatment. You will be offered a copy of this information by the study coordinator.

Statement by person agreeing to be in this study:

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date:
