Consent Form – Clinician and Students

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the purpose, benefits, and risks of the study and how it will conducted.

Mitigation Investigation for Spinal manipulation Treatments (MIST) – Part 2: Assessment & Feasibility of Electronic Post-Symptoms Evaluation

Parker University
Research Institute
2540 Walnut Hill Lane
Dallas, Texas 75229
www.parker.edu

Principal Investigator: Dr. Katherine Pohlman

Co-Investigators: Drs. Patrick Bodnar & Harrison Ndetan

Institution: Parker University Clinics

Introduction:

This study is being conducted with consultation from a scientist at the University of Alberta. You are being asked to participate in a research study because you provide chiropractic care to patients at the Parker University 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 and to better design future studies on this topic. In addition, it will also support patient safety, by helping clinicians and student interns be proactive in identifying patient safety concerns that their patients identify in this study. Before you make a decision regarding your participation, you will have an opportunity to discuss with one of the investigators. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form 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 you.

Compensation for Participants:

Food will be provided to those that participate in the focus group discussion at the end of the study.

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Risk/Benefit:
There are no known risks associated with participating in this study. It is not possible to know all of the risks that may happen in a study, but the investigators have taken all reasonable safeguards to minimize any known risks to a study participant.

You are not expected to get any benefit from being in this research study. The benefits of participating are helping to increase knowledge about the potential effects and safety after spinal manipulation therapy (aka adjustments) and may be used in consideration of future projects both within and outside Parker University.

Agreement to Participate:
We ask that all participating student interns under participating supervising clinicians to record the occurrence or absence of symptoms encountered during patient visits that will be identified by the study coordinator. For each of these visits, a study coordinator will invite your patients to complete two electronic surveys, which records their status before and after treatment (2-7 days). For all patients who agree to take part in the study, you (the intern) will need to complete a survey immediately after the patient's visit to see their immediate change in symptoms and provide the treatment you received. Adverse event identified by you or your patients and cleared with the patient for you to review will have an additional survey for you to complete with your supervising clinician.

In addition, you will be asked to participate in a focus group discussion after the study has been completed. This discussion will last approximately thirty minutes and food will be provided. During this interview, the investigators will assess the barriers and facilitators to participating in this research study.

Confidentiality:
During the study, we will be collecting data about the care provided to patients seen at Parker Clinics. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the investigator's office or published by the investigators. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.

Questions/Concerns:
If you have any questions regarding this research project, please feel free to contact the investigators. Their information is at the top of first page of this document.

Review for the Protection of Participants:
This research study has been reviewed and approved by the Parker Institutional Review Board (IRB). The Parker IRB can be contacted at (214) 902-2459 with any questions regarding the rights of research participants.

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Research Participant's Rights:

Your signature below indicates that you have read or have had read to you all of the above and that you confirm all of the following:

- The investigator(s) or their representative has explained the study to you and answered all of your questions. You have been told the possible benefits and the potential risks and/or discomforts of the study.
- You understand that you do not have to take part in this study, and your refusal to participate or your decision to withdraw will involve no penalty or loss of rights or benefits. The study personnel may choose to stop your participation at any time.
- Your decision whether to participate or to withdraw from the study will have no effect on your grade or standing at Parker University or within the clinic.
- You understand why the study is being conducted and how it will be performed.
- You understand your rights as a research participant and voluntarily give consent to participate in this study.
- You have been told you will receive a copy of this form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date