SafetyNET_4clinics Study Information

1) What is the purpose of this study?

This is a national research study looking at how to best collect information about your experience with chiropractic care, including safety information. You are being invited to take part because your chiropractor is participating in this project.

Scientists at Canadian Memorial Chiropractic College, Northeast University, and Parker University are doing this study. You are encouraged to ask questions. If you want to speak with one of the investigators, there is an opportunity to do so at the end of this consent form.

Participating in this study is your choice. If you decide to participate:
- you can change your mind and stop being in the study at any time (this will in no way affect the care you receive here; and
- a copy of this form will be sent to you via the email you provide to us (please check your "spam" or "junk" folders if you don't receive it).

Principal Investigators: Drs. Katherine Pohlman & Martha Funabashi
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Study Coordinator: Mr. Zakary Monier
zakmonier@parker.edu

Co-Investigators: Dr. William Owens
wowens@nationalspinemanagement.com

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

There are 3 main components to this study:

1. Surveys - You will be asked to complete 2 surveys, each taking 3-7 minutes to complete (depends on the amount of information shared).
- Survey 1 - Will be immediately following this consent form. This should be completed u before your treatment.
- Survey 2 (Follow-up) - Will be sent to you via email or text in 2 days. This survey should be completed within one week.
NOTE: Your survey findings may be shared with your chiropractor, who will answer additional questions about the feedback you provided.

2. Electronic Health Records - In addition information from the surveys, the team scientists are seeking your permission to obtain your health records from your chiropractor. Information gathered will be for study purposes only. This information will be sought after your chiropractor is done with the active participation portion of the study, thus will not impact your care in any way. This will also reduce the amount of information being sought from the study surveys.

3. Optional, Videoconference Interview - Because we are assessing how best to collect this information, a team member would like to discuss the study with you to see what worked well and what could be done better. You do not need to participate in this, but can choose to if you would like to assist the study team.

All individual information is confidential*. Only study investigators will have access to it. Others will only see results of all participants together with no identifiable information.

*- See 'Confidentiality' section for specific exceptions.

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 the risks that may happen in a study.

Some of the questions may be sensitive in nature. Please know that you can stop the survey at anytime and request to talk to a study investigator, if desired.

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 the lead investigator: Dr. Katherine A Pohlman at +1 419-733-1129 or kpohlman@parker.edu

You can also contact the Study Coordinator: Mr. Zakary Monier at zakmonier@parker.edu

This study has been reviewed by, and received ethics approval through Parker University's Institutional Review Board (IRB). In the event you have any comments or concerns resulting from your participation in this study, please contact: 563-508-7376

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

8) Confidentiality:

If you agree to complete the surveys of this study, we will collect data about the care you received. We will take all steps to ensure all data are kept private. All electronic data will be secured on the REDCap database with restricted access to only necessary personnel.

Exception to this:

- By law, we may have to release our data and the information you provided. In that case, we will make every legal effort to ensure your personal information is kept private.

- For ethical responsibilities, like if we discover unexpected clinical findings (i.e., mental health), your personal health information will be sent to your chiropractor. This will assist with referring you for appropriate care.

9) Authorization to Use/Disclose Personal Health Information

All efforts, within reason, will be made to keep your personal health information (PHI) confidential. PHI is your health information gathered or kept by your healthcare clinician as a result of the treatment they provided to you. This includes research information that can be traced back to you. Using or sharing such information must follow federal privacy rules. By signing the consent for this study, you are agreeing to the use and sharing of your PHI collected in this study. If you agree to be in this study, you are also agreeing to let the study team use and share your PHI as described below.

All data storage from REDCap will be at Parker University in Dallas, Texas with the lead investigator: Dr. Katie Pohlman (kpohlman@parker.edu). The study results will be kept for at least six years after the study is finished.

All electronic records from this study will be password-protected and encrypted, and stored on a secure server at Parker University. Records will only be released with your consent or by court order or as required by law. No publication that results from this study will use identifiable information such as your name.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, please contact Dr. Katherine A Pohlman in writing. Let her know that you withdraw your consent. Her mailing address is 2540 Walnut Hill Lane, Dallas, TX 75229. Her email address is kpohlman@parker.edu. At that time, we will stop getting any more information about you. The health data we stored before you withdrew your consent may still be used, unless otherwise stated by you in your withdrawal.

If you decide not to participate in this research study, it will not affect your treatment.

You will be sent a copy of this signed document via the email address that you provide.