LOMA LINDA UNIVERSITY HEALTH

Neuropathic Therapy Center

INFORMED CONSENT

TITLE: **NEUROPATHIC THERAPY CENTER RESEARCH DATABASE OF CLINICAL PATIENT DATA**

PRINCIPAL INVESTIGATOR: Mark Bussell, DPT,OCS Clinical Director of the Neuropathic Therapy Center

Key Information for You to Consider
• **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
• **Purpose.** The purpose of this research is to create a database of patient clinical data that can be used retrospectively for future research studies on treatment approaches for patients with neuropathic pain.
• **Duration.** It is expected that your clinical information will be safely stored in a database and may be accessed indefinitely by authorized research personnel, unless you inform us otherwise.
• **Procedures and Activities.** We are asking your permission to use your medical information for research purposes. Clinical data may then be accessed retrospectively for future research studies.
• **Risks.** A foreseeable risk of your participation include possible breach of patient data confidentiality.
• **Benefits.** There is no direct benefit, however your participation may help researchers gain more insight of treatment approaches for patients with neuropathic pain.
• **Alternatives.** Participation is voluntary and the only alternative is to not participate.

WHY IS THIS STUDY BEING DONE?

The purpose of the study is to enhance future research of nerve pain. Currently, the Neuropathic Therapy Center treats almost exclusively patients with nerve pain. Given the unique nature of the therapy and patient population, it would be best to harvest data from past patient charts. This data could include response to treatment, patient reports and outcome since such data does not presently exist. This information will be used to enhance future treatment for patients with neuropathic pain.

WHO WILL BE INVOLVED?

All data and documents from every consenting patient that is evaluated at the Neuropathic Therapy Center will be included in the study. Every patient will that is treated at the Neuropathic Therapy Center will have the opportunity to have their data and documents included with the study.

WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?

This study poses no greater risk to you than what you routinely encounter in day-to-day life. Participating in this study may involve the risk of breach of confidentiality. All records and research materials that identify you will be held confidential. Any published document resulting from future studies will not disclose your identity without your permission. Information identifying you will only be available to the study personnel.

All information on a computer will be password-protected, and all written files and paperwork will be kept in a locked file cabinet. Information accessed retrospectively will be de-identified prior to any analysis. The use of your Protected Health Information is explained in the separate authorization form.

WILL THERE BE ANY BENEFIT TO ME OR OTHERS?

There is no direct benefit, however retrospective analysis of patient clinical data may help researchers gain more insight into treatment approaches for patients with neuropathic pain.

WHAT ARE MY RIGHTS AS A SUBJECT?

Your participation in this study is entirely voluntary. You may refuse to participate or withdraw once the study has started. Your decision whether or not to participate or terminate at any time will not affect your relationship with Loma Linda University Health. You do not give up any legal rights by participating in this study.

WHAT COSTS ARE INVOLVED?

There is no cost to you for participating in this study.

You and/or your health insurance must pay for those services, supplies, procedures, and care required for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will not be paid to participate in this research study.

WHO DO I CALL IF I HAVE QUESTIONS?

Call 909-558-4647 or e-mail patientrelations@llu.edu for information and assistance with complaints or concerns about your rights in this study.

SUBJECT'S STATEMENT OF CONSENT

- I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I may call Mark Bussell, DPT, principal investigator, during routine office hours at (909) 558-6799 if I have additional questions or concerns.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

_____ _____

Signature of Subject | Printed Name of Subject

_____

Date

INVESTIGATOR'S STATEMENT

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

_____ _____

Signature of Investigator | Printed Name of Investigator

_____

Date