**CONFIDENTIAL WHEN COMPLETED**

# FREMS-PDPN Trial

The Utility of Frequency-Modulated Electromagnetic Neural Stimulation (FREMS) as a Third Line Treatment in Patients with Painful Diabetes-Related Peripheral Neuropathy: A Randomised Controlled Trial

## Screening Informed Consent Form

**Version 2.0 19th Jan 2023**

**Principal Investigator:** _____

**FREMS-PDPN Trial Number** ☐☐☐☐

**Please select 'Yes' for each box on the online form to confirm your consent**

| | | |
|---|---|---|
| 1 | I confirm that I have read and understood the **FREMS-PDPN** Participation Information Sheet version number __. __ dated _ _ /_ _ _ / _ _ _ _. I have also had enough opportunity to think about the information provided in information sheet and ask questions and have had these answered satisfactorily. | **Yes** ☐ **No** ☐ |
| 2 | I understand that my participation in this trial is entirely voluntary and I am free to withdraw from screening at any time without giving any reason and without effecting my legal rights or the quality of my medical care. | **Yes** ☐ **No** ☐ |
| 3 | I understand that for the purpose of the trial relevant sections of my medical notes might be looked at by responsible individuals from the **FREMS-PDPN** research team, the sponsor (University of Birmingham), regulatory authorities, or from the NHS trust to check if I meet the criteria to participate in the main **FREMS-PDPN** trial and to check that the screening process is carried out correctly. | **Yes** ☐ **No** ☐ |
| 4 | I agree to complete the pain diary as described in the Participant Information Sheet to help check if I meet the criteria to participate in the main **FREMS-PDPN** trial. | **Yes** ☐ **No** ☐ |
| 5 | Data collected that identifies me by name, i.e. this consent form and the screening entry form, will be transferred to the central organisers University of Birmingham Clinical Trials Unit where it will be held securely and confidentially, password protected and encrypted for security. I give permission for the transfer and storage of this data. | **Yes** ☐ **No** ☐ |

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|---|---|---|
| 6 | I understand that all data collected will be used for medical research purposes only and that I will not be identified in the analysis or reporting of any results. | **Yes** ☐ **No** ☐ |
| 7 | I understand that if I do not enter the main trial, this consent form and my data collected during the screening process will be deleted at BCTU two weeks (14 Days) after the date of this screening consent. | **Yes** ☐ **No** ☐ |
| 8 | **OPTIONAL:** I wish to receive a copy of this consent form via email.<br><br>If you select 'Yes`, please provide the email address below that you wish the consent form to be sent to.<br><br>Email…… | **Yes** ☐ **No** ☐ |
| 9 | **I voluntarily agree to take part in the screening assessments for the FREMS-PDPN trial.** | **Yes** ☐ **No** ☐ |

| Participant's full name | Participant's signature | Please confirm the date you, the participant signed this form: |
|---|---|---|
| | | D D M M M Y Y Y Y |

**Researcher taking consent**: I confirm that the nature of the FREMS-PDPN trial has been explained to the above named patient.

| Researcher's full name | Researcher's signature | Please confirm date researcher signed this form: |
|---|---|---|
| | | D D M M M Y Y Y Y |

**This consent form is now complete.**

**PARTICIPANT**: Thank you for agreeing to take part in the **FREMS-PDPN** trial. The researcher will now provide you with a printed copy of the consent form for your records. If you consented to receiving the form via e-mail, a copy will be sent to your e-mail address instead. If you did not receive a copy at the e-mail address you gave, please speak to the researcher or a member of the research team who will be happy to resolve this for you.

**RESEARCHER:** When completed please provide a copy to the participant. Please also retain a copy in the participant medical notes. A printed copy should be filed in the **FREMS-PDPN** Investigator Site File.

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