CONFIDENTIAL WHEN COMPLETED

<trial logo to be inserted here>

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

Main Informed Consent Form

Version 2.0 02nd Nov 2022

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** Main Participant Information Sheet version number __. __ dated _ _ /_ _ _ / _ _ _ _. I have also had enough opportunity to think about the information in the information sheet and ask questions, and I have had these answered satisfactorily.	**Yes** ☐ **No** ☐
2	I understand what will happen with my personal data collected for this trial and how this will be managed.	**Yes** ☐ **No** ☐
3	I understand that for the purpose of the trial relevant sections of my medical notes may 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 that the trial is carried out correctly.	**Yes** ☐ **No** ☐
4	I understand that my participation in this trial is entirely voluntary and that I am free to withdraw at any time, without giving any reason and without affecting my legal rights or the quality of my medical care. I understand that the data collected up to the point of my withdrawal will be kept and used.	**Yes** ☐ **No** ☐

5	Data collected that identifies me by name, i.e. this consent form and the trial 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** ☐
6	I understand that all data collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results.	**Yes** ☐ **No** ☐
7	My preferred method of contact is: (please select one ONLY) Email (email please provide email address below) ☐ Mobile number (please provide number below) ☐ Email address (please leave blank if email is not the preferred method of contact) …… Mobile Number (pleased leave blank if mobile is not the preferred method of contact) 0 ☐☐☐☐☐☐☐☐☐☐	
8	I agree to the study coordinators sending me an online link or text message to complete the electronic questionnaires via my preferred method of contact as I have indicated in Point 9.	**Yes** ☐ **No** ☐
9	I agree to my GP being informed of my participation in this trial.	**Yes** ☐ **No** ☐
10	I give permission for my research team to access previously taken blood samples (if applicable) for eligibility purposes.	**Yes** ☐ **No** ☐
11	**OPTIONAL:** I give permission to be followed up after my participation in FREMS-PDPN trial has ended. This may be for up to 10 years after the end of the trial This may involve linkage of my data available in NHS routine clinical datasets, including primary care data (e.g. Clinical Practice Research Datalink, The Health Improvements Network,	**Yes** ☐ **No** ☐

	QResearch) and secondary care data (Hospital Episodes Statistics) through NHS Digital and other central NHS bodies.	
12	**OPTIONAL Sub-Study: Liverpool and Sheffield Sites Only.** I agree to take part in the optional Quantitative sensory testing (QST) sub-study.	**Yes** ☐ **No** ☐
13	**OPTIONAL:** I wish to receive a copy of this consent form via email. If you select 'Yes`, please provide the email address below that you wish the consent form to be sent to.	**Yes** ☐ **No** ☐
	If you have provided an email address in point 7 and wish to use the same email, please select 'As above` Another email (please provide below) ☐ As Above ☐ **Email Address……**	
14	**I voluntarily agree to take part in the Main 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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