UNIVERSITY OF LEEDS

The Leeds Teaching Hospitals NHS Trust

Informed consent form

version 2.0

A Randomised, Single-blind, Sham-controlled, Crossover Pilot Study Assessing the Effect of Non-invasive Vagus Nerve Stimulation (nVNS) on Autonomic Symptoms and Pain Management in Patients With Chronic Musculoskeletal Pain and Autonomic Dysfunction

Reducing sympathetic tone with nVNS for MSK pain relief

(RESTORE-MSK)

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NCT number:

RESTORE-MSK ICF V2.0 (14-1-2026).docx

PATIENT CONSENT FORM

RESTORE-MSK:

Reducing enduring sympathetic tone with non-invasive vagus nerve stimulation (nVNS) to optimise relief in chronic musculoskeletal (MSK) pain

Patient ID:	__ __ __	**Initials:**	__ __ __

Patient to initial each point

1. I confirm that I have read and understand the patient information sheet dated _____ (version _____) for the above study and have had the opportunity to ask questions.

   I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I agree to take part in the study. .....

2. I understand that my research records may be looked at by authorized individuals from the Sponsor for the study, the NHS Trust, the UK Regulatory Authority, in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study and any further research that may be conducted in relation to it. .....

3. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication. .....

4. I agree that my GP, or any other nominated doctor, will be notified of my participation in this study. .....

5. I give permission for the research team to access my medical records to collect information relevant to this study, including demographic information, medical history, diagnosis, disease duration, comorbidities, and medication history. I understand this information will be anonymised and stored securely using only my study ID code. .....

6. (optional) I consent to the transfer of my anonymised data to other research groups within the UK or internationally for research purposes, including publication use. .....

7. *(optional) I would like to receive a summary of the study results. I consent to providing my email for this purpose. Email: _____* .....

_____	_____	____ / ____ / _____
Name of the Patient	**Participant's signature**	**Date of signature**
_____	_____	____ / ____ / _____
Name of the Investigator	**Investigator's signature**	**Date of signature**

Original to be retained and filed in the site file. 1 copy to patient, 1 c