# Informed Consent
# Diagnostic Accuracy of the Water-Immersion Wrinkle Test for the Diagnosis of Small-Fiber Neuropathy

Principal Investigator: Dr. Lucas A. Piedrafita Vico – Hospital Británico de Buenos Aires.

NCT – pending assignment

October 9, 2024

By means of this document, we invite you to authorize us to collect information from your medical record, to perform the water-immersion wrinkle test, and to take photographs of the fingertips of your hands, given that you have been diagnosed with small-fiber neuropathy. This type of neuropathy may be characterized by sensory symptoms (loss or reduction of perception of cold and/or heat, altered nociceptive sensation [pain]) and may be accompanied by unpleasant symptoms (paresthesias such as tingling, pins and needles, burning).

## Description of the Research Study

Based on your medical history, we will transcribe your clinical data and the results of your tests using only a code that includes the initials of your name and your date of birth. This neuropathy poses diagnostic challenges due to the complexity of its manifestations and the currently available diagnostic tests. The water-immersion wrinkle test (WIWT) is a simpler, noninvasive, painless, and accessible tool that has the potential to make a valuable contribution to the initial diagnosis of your neuropathy, supporting the final diagnosis. The test involves immersing both hands in warm water (at 44-43°C) for 15 minutes and then observing the wrinkles that form on your fingertips; these provide information about the fibers affected in your neuropathy. We plan to compare this test with other tests that you have undergone because they are the traditional diagnostic methods for your neuropathy (such as quantitative sensory testing [QST], nerve conduction studies, and the sudomotor sympathetic response [SSR]) in order to assess the future usefulness of WIWT and help improve the comprehensive diagnosis of your neuropathy.

## Potential Benefits

You will not receive any direct benefit for authorizing the collection of your health data and for undergoing the water-immersion wrinkle test; however, it is expected that this information will allow us to better understand the usefulness of the test and thereby improve the initial diagnosis of patients with small-fiber neuropathy. You are not expected to experience any risk or harm from allowing access to your data and undergoing this test. The treatment you receive for your condition will not be affected in any way.

## Will my participation in the study be kept confidential?

All personal information we collect will be kept confidential on a computer accessible only to the physicians responsible for this study from the Department of Neurology at Hospital Británico de Buenos Aires. This database will be maintained in strict confidentiality and may only be viewed by the study investigators and by the Ethics Committee authorities, in accordance with the Personal Data Protection Law (Habeas Data Law No. 25.326). Your name will not be disclosed in any report or publication; instead, you will be identified by your initials and date of birth. The data and results of this study may also be presented at scientific meetings or in publications, but in such presentations the identities of the individuals participating in the study

will be kept confidential. By signing this form, you or your legal representative authorize such access.

## Communication of Results – New Information

You may contact Dr. Lucas Piedrafita Vico (11-5958-8888) from the research team and Ms. Luciana Casella (43096892 – Institutional Review Board) at any time to obtain information about the progress of the study or its general results. You will be informed of any relevant data or new information that arises during the course of the study and that may be of diagnostic or therapeutic interest to you.

## Withdrawal from the Study

You may withdraw from this study at any time without this affecting your subsequent medical care.

## Costs

Participation in this study will not entail any expenses of any kind for you.

## Voluntary Participation

Your participation is entirely free and voluntary. Your decision will not affect the quality of the health services you receive. You may take time to reflect and discuss your participation with peers or family members before giving us an answer. You are also free to withdraw from the research project at any time.

If you have questions about your rights or ethical issues related to your participation in this research study, you may contact the Ethics Committee of this hospital (Ms. Luciana Casella, phone 43096892) or the investigator. You are also informed that you may be selected by the Institutional Review Board (Comité de Revisión Institucional) to be interviewed regarding your understanding of and agreement with the study. Thank you for reading this document. We are at your disposal to answer any questions you may have.

**Investigators**

Dr. Lucas Piedrafita Vico: 11-5958-8888

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**Informed Consent Declaration**

I, ..... (full name of the patient or responsible family member), confirm that I have read—or have had read to me—this informed consent form. I understand the information presented and my questions have been answered. I understand that I will receive a copy of this form. I voluntarily consent to authorize the health professionals at Hospital Británico de Buenos Aires to collect information from my medical record, to perform the water-immersion wrinkle test, and to take photographs of the fingertips of my hands. All of the above is related to evaluating the usefulness of the test under study for the diagnosis of small-fiber neuropathy, so that it may be used in future studies.

**Preservation of Information and Anonymous Photographs**

[ ] I accept / [ ] I refuse that my information and photographs be used in other research after this study has ended.

By signing this consent, I am not waiving my legal rights, nor am I releasing the investigator or the hospital from their civil or professional obligations.

| Patient's Signature | Printed Name and ID | Date of Signature |
|---|---|---|
| _____ | _____ | _____ |

I confirm that I have explained the nature and purpose of this study to the above-named patient, and that I have complied with the Declaration of Helsinki of the World Medical Association and the regulatory documents required by the Institutional Review Board of Hospital Británico de Buenos Aires, which has evaluated and approved this study and will verify compliance with all conditions regarding the participant's safety and rights.

| Investigator's Signature | Investigator's Name and ID | Date of Signature |
|---|---|---|
| _____ | _____ | _____ |