Research Participant Identification No.: ....

INFORMED CONSENT FORM FOR VOLUNTEER PARTICIPANTS IN A RESEARCH STUDY

[English translation of source pages 1–2 provided]

Research title:	A 50-week, randomized, double-blind, multicenter study comparing treatment of hemifacial spasm with abobotulinum toxin A (Dysport) 100 units versus neubotulinum toxin A (Neuronox) 33.33 units.
Principal Investigator:	Subsai Kongsaengdao, M.D. Neurology Unit, Department of Medicine, Rajavithi Hospital 2 Phaya Thai Road, Ratchathewi, Bangkok 10400 Tel. 081-818-0890 or 02-354-8108 ext. 60119
Site Investigator:	Pichai Rojanapithayakorn, M.D. Neurology Unit, Department of Medicine, Surat Thani Hospital 56 Kor, Si Wichai Road, Makham Tia Subdistrict, Mueang District, Surat Thani 84000 Tel. 077-915600 ext. 4329 Mobile 089-168-0232

By signing and dating this informed consent form, I confirm that:

1. I have received an explanation from the research team regarding the background, purpose and objectives of the study, the study procedures, the risks and benefits that I may receive, including any compensation.
2. I have had sufficient time to read the Participant Information Sheet in detail and have received explanations until I understand the information provided to volunteers for this study.
3. I have had the opportunity to discuss the study and ask questions until I am satisfied with the answers and explanations received.
4. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without having to provide any reason, and that my withdrawal will not affect my medical care or legal rights.
5. I agree that my medical information may be used specifically for this research. I understand that my de-identified personal information may be sent to the research sponsor at Rajavithi Hospital and may be submitted to the Thai Food and Drug Administration for consideration of drug registration or may be used in accordance with other applicable study agreements.

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6. I have the right to access my information and to request correction of my health information that I have provided at any time.
7. If I benefit from the research, or if I believe that I may be at risk of or have suffered harm from participating in the research, I authorize the investigator to inform my treating physician of such findings.
8. I agree to participate in this study.
9. I acknowledge that the legally responsible representative has received a detailed Participant Information Sheet and has received a signed copy of this informed consent form bearing the date and signature, totaling one copy.

SIGNATURES

Name-Surname _____ Research Participant Date _____ / _____ / _____

(_____)

Name-Surname _____ Person Obtaining Consent Date _____ / _____ / _____

(_____)

Name-Surname _____ Witness Date _____ / _____ / _____

(_____)

If the volunteer or parent/legal representative is illiterate or unable to read or write:

(Thumbprint)

(_____)
Research Participant
Date _____ / _____ / _____

Name-Surname _____ Person Obtaining Consent Date _____ / _____ / _____

(_____)

Name-Surname _____ Witness Date _____ / _____ / _____

(_____)

Name-Surname _____ Witness Date _____ / _____ / _____

(_____)