« Development and first evaluation of the validity and reliability of the NeuroFibromas Area Severity Index (NeF-ASI), severity index related to cutaneous neurofibromas in type 1 neurofibromatosis"
NeF-ASI

This research is under the responsibility of
Dr Laura FERTITTA, Department of Dermatology, Hôpital Henri Mondor, Créteil 94, France

PARTICIPANT INFORMATION NOTE v1-0 of 12/07/2021

Dear participant,

Doctor Laura Fertitta, practicing at Henri Mondor Hospital, Créteil France, hereby provides information regarding the following online survey dedicated to the validation of the measurement tool NeF-ASI evaluating the cutaneous severity associated to the cutaneous neurofibromas in individuals living with neurofibromatosis type 1 (NF1). It is important to read this note carefully; If you have any further questions, please don't hesitate to contact us directly.

1) What is the goal of this research?

New molecules targeting cutaneous neurofibromas are being studied and will soon be the subject of therapeutic trials. In this perspective, the definition of outcomes and their measuring instruments is necessary.
The objective of the research is the validation of a digital tool accessible on a dedicated website. This tool aims to evaluate the cutaneous severity related to cutaneous neurofibromas in individuals with NF1. This is an international online survey. It is planned to collect the opinion of approximately 20 participants, health professionals, experts or not in NF1.
If you agree to participate in this study, you will be given access codes to access a secure website dedicated to the NeF-ASI tool. You will be required to complete an anonymous questionnaire that includes demographic and professional data about you. You will also have to evaluate 50 images using our NeF-ASI tool, the estimated total time required is a maximum of 1 hour, to be distributed at your discretion over an interval of a maximum of 7 days. The selected answers cannot be modified afterwards. This evaluation will be repeated at 15-day intervals.

2) What is the research schedule?

The estimated duration of the research is approximately 12 months. Personal data (month and year of birth, sex, profession, quality of expert or not, service and country of practice) and the scores assigned to the images will be collected as part of 2 surveys (15 days apart each).

3) If you participate, how will the data collected for the research be processed?

The responses to the survey are collected online, via a connection to the website address of the website dedicated to the NeF-ASI tool.
Anonymized processing of your personal data will be implemented to allow analysis of the results. These data will be identified by a registration number. The computer file used for this research is implemented in accordance with French regulations (amended Data Protection Act) and European (General Data Protection Regulations - GDPR). You have the right to access, rectify, erase and oppose to the processing of data covered by professional secrecy used in the context of this research. These rights are exercised with the doctor in charge of the research, who alone knows your identity (identified on the first page of this document).

If you wish to object to the use of your data for this research, you just have to tell the doctor in charge of the study (laura.fertitta@aphp.fr or postal mail: Dr Laura FERTITTA, Dermatologie, CHU Henri Mondor, 1 av. Gustave Eiffel 94010 Créteil). Your decision will not result in any prejudice and the data collectedbwill be erased.
In case of difficulties in exercising your rights, you can also contact the Data Protection Officer of the APHP central office at the following address protection.donnees.dsi@aphp.fr, who will be able to explain to you in particular the remedies available to you with the CNIL. You can also exercise your right to complain directly to the CNIL (for more information on this subject, visit the website www.cnil.fr).

4) How is this research framed?

The data controller has taken all measures to conduct this research in accordance with the provisions of the Public Health Code applicable to research not involving humans. This research falls within the framework of the "Reference Methodology relating to the processing of personal data implemented within the framework of research not involving the human person, studies and evaluations in the field of health" (MR- 004). The research manager signed a commitment to comply with this "Reference Methodology" and the research was registered in the public directory of the Health Data Hub.

This research is registered locally with the data protection officer.
The research obtained a favorable opinion from the Research Ethics Committee / IRB of Henri Mondor University Hospitals on 09/15/2022.

5) What are your rights?

Your participation in this research is entirely free and voluntary. If you do not wish to participate in the research, all you have to do is tell the doctor conducting this investigation, which will have no consequences on your relations with the dermatology department of the Henri Mondor hospital. You will be able, throughout the research and at the end, to request information concerning the progress of the research from the doctor conducting this investigation.
You can withdraw at any time from the research without justification, without consequence, in this case, the data collected until your withdrawal will not be used later or for another research.
At the end of the research and after analysis of the data, you can be informed of the overall results of the research by asking the doctor who contacted you to participate in this research.
Your data will only be kept for a period strictly necessary and proportionate to the purposes of the research. They will be kept in the computer systems of the data controller for up to 2 years after the last publication of the research results. Your data will then be archived according to the legislation in force.

After reading this information, discussing all aspects with the doctor in charge of this study and, if you wish, having been able to benefit from additional time for reflection, if you agree to participate in the research, please confirm your consent by connecting to the dedicated website using the private access codes that will be communicated to you.
At the end of the information, the mention: "Click on I AGREE TO PARTICIPATE IN THE STUDY if you agree to participate", appears and gives access to the items of the questionnaire.

Collection of your non-objection after reading the information note
Date of knowledge of the information: DD / MM / YYYY
Click on NEXT if you do not object to participating