

A Study to Evaluate the Feasibility of a Physiologic Biomarker to Assess Pain and Other Sensory Problems Using Pupillometry in Participants With Neurofibromatosis Type 1 (NF1)

NCT06507748

Status	RECRUITING
Phase	Not Applicable
Sponsor	National Cancer Institute (NCI)
Enrollment	70 participants

Key Eligibility Criteria

Inclusion (6)

- History of clinical or genetic diagnosis of NF1 as per the 2021 revised diagnostic criteria
- Age \geq 1 year
- At least one digit (finger or toe) without open wounds for application of the device
- Individuals must understand English or Spanish
- Individuals who are $<$ 18 years must have a caregiver willing to help the child engage in study procedures, assist with fitting the AlgometRx Nociometer (Registered Trademark) device, and complete the observer reported (ObsRO) measures. Note: the caregiver of a child participant \geq 5 years old must be able to understand English or Spanish, the caregiver of a child participant 1-4 years old must be able to understand English (to help complete the observational pain measure for the younger children that is only available in English)
- ... and 1 more (see full listing online)

Exclusion (3)

- History of eye pathology which precludes pupillometry, such as problems with pupillary reflex, blindness or inability to open at least one eye fully for evaluation
- Individuals with chronic use of medication that specifically affects their pupillary response, such as atropine-containing eye drops
- Uncontrolled intercurrent illness evaluated by medical history that would potentially increase in risk of participant

Locations (2 total)

Children's National Medical Center, Washington D.C., District of Columbia, United States
National Institutes of Health Clinical Center, Bethesda, Maryland, United States