1. Date of test:
2. Outcome (choose all that apply):

Pain threshold

Sensory detection threshold

Pain tolerance threshold

Other, specify:

* 1. Please define the type of outcome(s) chosen above:

1. Type of stimulation (choose all that apply):

Heat

Cold

Pressure

Vibration

Electrical

Other, specify:

1. Body site stimulated:
2. Number of times test was performed:

If more than one, specify method used to combine data from individual tests:

1. Timing of recordings:  ictal  inter-ictal  peri-ictal
   1. If ictal, pain intensity at time of recordings:
   2. If ictal, duration of time since onset of headache (include units):
   3. If inter-ictal or peri-ictal, duration of time since end of last headache (include units):
   4. If inter-ictal or peri-ictal, duration of time until start of next headache (include units):
2. Testing methodology: (choose all that apply)

Method of limits  Method of levels  Other methodology used, specify:

1. Equipment used for testing:
2. Safety parameters for testing:
   1. Maximum intensity of stimulation (e.g. maximum temperature, maximum pressure; include units of measurement):
   2. Maximum duration of stimuli (include units):
   3. Were there any data points that would have exceeded the safety parameters noted above?

Yes  No

* + - 1. If Yes, specify how these data points were handled statistically:

1. Number of examiners performing QST throughout the study:
2. Thermode/electrode size (include units):
3. Rate of increase of stimulation (e.g. o Celsius/second):  N/A
4. Rate of decrease of stimulation (e.g. o Celsius/second):  N/A
5. Stimulus duration (include units):
6. Frequency of vibration or electrical stimuli used (include units):  N/A
7. Intensity of pain resulting from stimulation on a scale from 0-10 (e.g. 0 = No pain, 10 = Most severe pain):
8. Duration between stimuli/intertrial intervals (include units):
9. Participant’s/subject’s baseline skin temperature:  ○F  ○C
10. Exam room temperature at the time of testing:  ○F  ○C

## General Instructions

This CRF contains questions that should be answered when Quantitative Sensory Testing (QST) is used in headache research.

Important note: All elements on this CRF are considered Exploratory for sickle cell disease and should only be collected if the research team considers them appropriate for their study.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Date of test –Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ([Click here for International Standard for Dates and Times](http://www.iso.org/iso/home.html)). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
* Outcome – Choose all that apply and define the type of outcome(s) chosen. Investigators should provide a definition of the threshold used in their particular study.
* Type of stimulation – Choose all that apply
* Body site stimulated – Indicate body location that was stimulated.
* Number of times test was performed –If more than one, specify method used to combine data from individual tests. No additional instructions
* Timing of recordings – report the timing of recordings in relation the headache. The precise time windows for peri-ictal and inter-ictal vary with headache type. For episodic migraine, an interval of at least 72h from the last and before the next attack is generally accepted for “inter-ictal”.
* Testing methodology – Choose all that apply
* Equipment used for testing – Report specifications of equipment used for testing (e.g. make, model)
* Maximum intensity of stimulation – Examples include maximum temperature and, maximum pressure. Include units of measurement. Report maximum intensity of stimulation that was allowed during the testing, if applicable.
* Maximum duration of stimuli – Report the maximum duration of stimulation that was allowed during the study, if applicable.
* Were there any data points that would have exceeded the safety parameters noted above? – If yes, specify how these data points were handled statistically. At times, a subject’s actual sensory threshold of interest exceeds a safety limit placed on the testing. For example, when testing heat pain thresholds, it is possible that a subject would not find stimulation with the maximum allowable temperature to be painful. The investigator should describe how such occurrences were handled statistically.
* Number of examiners performing QST throughout the study – The purpose of this element is to determine whether or not QST was performed by one investigator or more than one investigator.
* Thermode/electrode size – Include units
* Rate of increase of stimulation – No additional instructions
* Rate of decrease of stimulation – No additional instructions
* Stimulus duration – No additional instructions
* Frequency of vibration or electrical stimuli used – Include units
* Intensity of pain resulting from stimulation on a scale from 0-10 - Example: 0 = No pain, 10 = Most severe pain
* Duration between stimuli/intertrial intervals – No additional instructions
* Participant’s/subject’s baseline skin temperature – No additional instructions
* Exam room temperature at the time of testing – No additional instructions

## References

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Rolke P, Magerl W, Andrews Campbell K, et. al. Quantitative sensory testing: a comprehensive protocol for clinical trials. European Journal of Pain 2006;10:77-88.

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