MULTIPLE SLEEP LATENT TEST (MSLT) Manual of Operations for NSRR

1) GENERAL OVERVIEW

9/1/1989: Research MSLT's started

8/7/2001: Started to do some Clinical MSLTs in addition to the Research MSLTs

9/6/2003: No longer doing Research MSLTs, only Clinical MSLT's

12/11/2001 - 7/1/2004: A special subset of individuals with subject Id's starting with the letter "N" were invited to participate in the overnight study and clinical MSLT. These individuals were identified according to their responses on SURVEY 3 that pertained to traditional Narcolepsy symptoms, who had not previously participated in the sleep cohort study.

2) RECORDING PROCEDURES, SCORING CRITERIA AND PROTOCOL FOR RESEARCH AND CLINICAL MSLT

BEGINNING OF THE TEST

- Starting Time:
 - The **research** MSLT protocol begins at approximately 9:00 am, with four naps at two-hour intervals.
 - The **clinical** MSLT protocol occurs on the morning after an overnight polysomnography (PSG). The clinical study begins approximately 2 hours after morning wake-up, with four to five naps at two-hour intervals. The clinical study ends after four naps if there is no Sleep-Onset REM Period (SOREM), or if there are two or more naps with SOREM. A fifth nap is performed if there is one nap with SOREM, or uncertainty about SOREM in any of the naps.
- Subject should remove shoes, loosen constricting clothing, and be hooked up in bed 5 minutes before scheduled start of test.
- Have subject complete subjective rating of sleepiness.
- Perform physiological calibrations EC, EO, look left, look right, look up, look down, blink, clench teeth, entering the corresponding annotations as they occur.
- Encourage subject to assume a comfortable position for falling asleep. (NOTE: This is done *before* test instructions are given.)
- The following instruction is repeated verbatim for every MSLT:
 - "Please lie still, keep your eyes closed, and try to fall asleep if you can. I will let you know when the test is over."
- o Immediately after instructions are given, lights are turned off, signaling the start of the test, from which time (zero) sleep latency is calculated. Enter annotation for lights out when lights out occurs, making every effort to place at the beginning of an epoch.

ENDING A TEST

The research MSLT is terminated 20 minutes after lights-out:

if there has been no sleep,

OR after three consecutive epochs of Stage 1 sleep,

OR after the first epoch of another sleep stage.

The **clinical** MSLT ends 15 minutes after the first epoch of sleep, or after 20 minutes from lights out if sleep has not occurred within that time.

The sleep tech recording the clinical MSLT determines sleep onset by scoring "on the fly", continuing until there is an epoch of unequivocal Stage 1 sleep, from which point the recording continues for 15 minutes. This sleep onset latency may decrease when reviewing and scoring the naps retrospectively but ensures that the nap does not end prematurely.

Stage 1 sleep defined:

A relatively low voltage, mixed frequency EEG with a prominence of activity in the 2-7 cps range. Stage 1 is characterized by the presence of slow eye movements, each of several seconds duration, which are usually most prominent during the early portions of the stage. Rapid eye movements are absent.

The transition from a low voltage waking record to Stage 1 is characterized by a generalized slowing of the EEG. The transition from an alpha record to Stage 1 is characterized by a decrease in the amount, amplitude, and frequency of alpha activity.

When the amount of record characterized by alpha activity combined with low voltage activity drops to less than 50% of the epoch and is replaced by relatively low voltage, mixed frequency activity, the epoch is scored as Stage 1.

MEASURING LATENCIES

Sleep latency is measured as the elapsed time from lights-out to the first epoch scored as sleep using a 30-sec scoring epoch. This criterion is reached when sleep occupies > 50% of any 30-sec epoch.

Sleep onset is determined using the standard sleep stage criteria. In cases where there is no clear slowing in the central derivations for \geq 15 sec., the occipital derivations should be compared with the centrals to determine the percentage of sleep in an epoch.

Latency to SOREM is measured beginning with the first epoch after the epoch of sleep onset.

QUALITY ASSURANCE

A technical evaluation of the recording will be done by the lab manager prior to scoring based on the following criteria:

- 1. The record is clearly annotated with lights-out, lights-on, and any other information that affects scoring.
- 2. The recording was not terminated prematurely (e.g., before the onset of sleep).
- 3. The recording does not contain excessive amounts of artifact which would make the record unscoreable and that a sufficient number of attempts were made to alleviate artifact when possible.

SCORING PROCEDURES

Scoring of MSLTs is done by two individual scorers (one of which is the lab manager) who have been qualified to do scoring based on a minimum of 50 scored records. Clinical MSLTs are scored by the recording technologist and the Lab Manager.

Each study is scored individually without knowledge of the results of the other scorer, recording sleep onset for each nap on a separate scoring sheet.

The scorers will make comments on the <u>scoring sheet</u> to provide information when further review is necessary.

The individual scores are compared, and the final scores and latency recorded on the <u>data sheet</u> using the following criteria:

- 1. If the scores differ by < 2 min., the scores are averaged.
- 2. If the scores differ by > 2 min., the scorers confer with each other and try to come to an agreement, with the lab manager being the arbiter when no agreement can be reached.

For the clinical MSLT, REM is determined based on R&K scoring guidelines. When a SOREM is detected within the 15 minutes following sleep onset, every effort is made to be in agreement on sleep onset and consequently REM latency. If the difference between sleep latencies is less than 2 minutes, then the two subsequent REM latencies are averaged, and the mean REM latency recorded on the data sheet with a comment made that the value is the mean REM latency.

The final scores, mean latency, and occurrence of SOREM are recorded on the <u>data sheet</u> and are initialed by the person confirming the scores.

In most cases the scorer who completes the data sheet puts his/her scores in Column 1 and the other scorer's sleep latencies in Column 2.

The scorers will make comments on the <u>data sheet</u> to document by which criteria the scores were determined.

EDF CHANNEL LABELS (MSLT):

| | Grass Comet | Lab Based S | ystem (2009 | -present) | | | | |
|--------------|--------------------|--------------|-------------|-----------|-----------------------|--------------------|--------------------|--|
| df channel # | channelName | type ▼ | input1 🔻 | input2 🔻 | samplingRate 💌 | lowFilter 💌 | HighFilter ▼ | Comment |
| 1 | LEOG_M2 | EOG | LEOG | M2 | 200 | 0.3 | 35 | |
| 2 | REOG_M1 | EOG | REOG | M1 | 200 | 0.3 | 35 | |
| 3 | C3-M2 | EEG | C3 | M2 | 200 | 0.3 | 35 | |
| 4 | C4-M1 | EEG | C4 | M1 | 200 | 0.3 | 35 | |
| 5 | O1-M2 | EEG | 01 | M2 | 200 | 0.3 | 35 | |
| 6 | O2-M1 | EEG | 02 | M1 | 200 | 0.3 | 35 | |
| 7 | Chin1-Chin2 | EMG | Chin1 | Chin2 | 200 | 10 | 70 | Chin3 also collected and re-referenced when needed |
| 8 | EKG1-EKG2 | EKG | EKG1 | EKG2 | 200 | 0.3 | 35 | |
| | Grass Herita | go Sustam /2 | 2000 2000) | | | | | |
| | Grass Herita | ge System (2 | .000-2009) | | | | | |
| f channel # | channelName | type ▼ | input1 | input2 | samplingRate - | lowFilter ~ | HighFilter | Comment |
| 1 | L EOG | EOG | LEOG | A2 | 100 | 0.3 | 30 | |
| 2 | R EOG | EOG | REOG | A1 | 100 | 0.3 | 30 | |
| 3 | L CENT | EEG | C3 | A2 | 100 | 0.3 | 30 | |
| 4 | R CENT | EEG | C4 | A1 | 100 | 0.3 | 30 | |
| 5 | LOCC | EEG | 01 | A2 | 100 | 0.3 | 30 | |
| 6 | R OCC | EEG | 02 | A1 | 100 | 0.3 | 30 | |
| 7 | Chin EMG | EMG | EMG 1 | EMG 2 | 100 | 10 | 30 | EMG 3 also collected and re-referenced when needed |
| 8 | ECG | EKG | ECG1 | ECG2 | 100 | 3 | 30 | |

3) DATA ENTRY FORMS

- A) In Lab Questionnaire before the MSLT
- B) Sleep Log the week before the MSTL one version for Research MSLT and one version for Clinical MSLT because they represent different days. Reminder that the Clinical MSLT happens after an overnight PSG and so there is no diary data that day.
- C) Stanford Sleepiness Scale
- **MSLT Technician Data Sheet**

A) In Lab Questionnaire before the MSLT

Scor Sleep Research Laboratory

Multiple Sleep Latency Test

Questionnaire

(Oracle Data Table: MSLT)

| ID# | Suh | i id) |
|------|-----|-------|
| 1U # | Sub | ı ıu, |

| 1) | At what time did you go to sleep and wal | e up over the last two days? | | | | |
|------|---|--|--|--|--|--|
| Las | st night: bedtime0 | This morning: waketime0 | | | | |
| Nig | ght before last: bedtime1 | Yesterday morning: waketime1 | | | | |
| 2) | Was your nights sleep as usual? | | | | | |
| | Last Night: (SLQ1) | Night Before Last: (SLQ2) | | | | |
| | a. <u>1</u> Much Better | a. <u>1</u> Much Better | | | | |
| | b. 2 A little better | b. 2 A little better | | | | |
| | c. 3 As usual | c. <u>3</u> As usual | | | | |
| | d. <u>4</u> A little worse | d. <u>4</u> A little worse | | | | |
| | e. <u>5</u> Much worse | e. <u>5</u> Much worse | | | | |
| 3) | Are you feeling any discomfort today? | Yes No (discomfort) | | | | |
| 4) | Did you have any coffee or other stimula | nts this a.m.? Yes No (precoffee) | | | | |
| 5) | Will you be able to go until 4:30 p.m. tod without smoking cigarettes ½ hour before | ay without having any coffee or drinks containing caffeine and/or e each nap?Yes No (postcoffee) | | | | |
| CK T | O TOP BACK TO DATA ENTRY FORMS | | | | | |

BA

B) Sleep Log the week before the MSTL – one version for Research MSLT and one version for Clinical MSLT because they represent different days. Reminder that the Clinical MSLT happens after an overnight PSG, so there is no diary data that day.

Research MSLT Sleep log (Table: MSLT)

We would like to get an idea of your "normal" sleeping pattern to help us interpret your nap study. Please complete this sleep log for the week before your nap study. (Or as much as you can manage.)

| Day | Example: Sunday August 12 | | | | | | |
|---------------------------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Time you work up | 7:00 am | (waketime6) | (waketime5) | (waketime4) | (waketime3) | (waketime2) | (waketime1) |
| Any naps? | Yes | (naps_yn6) | (naps_yn5) | (naps_yn4) | (naps_yn3) | (naps_yn2) | (naps_yn1) |
| Time spent napping | 30 minutes | (naptime6) | (naptime5) | (naptime4) | (naptime3) | (naptime2) | (naptime1) |
| Time you went to sleep | 11:45 pm | (bedtime5) | (bedtime4) | (bedtime3) | (bedtime2) | (bedtime1) | (bedtime0) |

Clinical MSLT Sleep log (Table: MSLT)

ID (Subj_id)

We would like to get an idea of your "normal" sleeping pattern to help us interpret your nap study. Please complete this sleep log for the week before your nap study. (Or as much as you can manage.)

| Day | Example: Sunday August 12 | | | | | | |
|---------------------------------|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Time you work up | 7:00 am | (waketime7) | (waketime6) | (waketime5) | (waketime4) | (waketime3) | (waketime2) |
| Any naps? | Yes | (naps_yn7) | (naps_yn6) | (naps_yn5) | (naps_yn4) | (naps_yn3) | (naps_yn2) |
| Time spent napping | 30 minutes | (naptime7) | (naptime6) | (naptime5) | (naptime4) | (naptime3) | (naptime2) |
| Time you went to sleep | 11:45 pm | (bedtime6) | (bedtime5) | (bedtime4) | (bedtime3) | (bedtime2) | (bedtime1) |

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C) Stanford Sleepiness Scale

CLINICAL MSLT/STANFORD SLEEPINESS SCALE

(Table: MSLT) (Red indicates clinical_mslt only)

ID# _subj_id__

We would like you to rate how sleepy you feel right now. The scale ranges from 1 to 7, with 7 being the most sleepy. Please read the entire scale below and <u>check the level that best describes your current state of sleepiness:</u>

| First Trial/Time: sleepy1 |
|--|
| 1 feeling active and vital; alert; wide awake |
| 2 could function at a high level, but not quite at peak; able to concentrate |
| 3 relaxed, awake, responsive, but not at full alertness |
| 4 a little foggy, not at peak, let down |
| 5 fogginess, beginning to lose interest in staying awake; slowed down |
| 6 sleepiness; prefer to be lying down; fighting sleep; woozy |
| 7 almost in reverie; sleep onset soon; losing struggle to remain awake |
| Second Trial/Time: sleepy2 |
| 1 feeling active and vital; alert; wide awake |
| 2 could function at a high level, but not quite at peak; able to concentrate |
| 3 relaxed, awake, responsive, but not at full alertness |
| 4 a little foggy, not at peak, let down |
| 5 fogginess, beginning to lose interest in staying awake; slowed down |
| 6 sleepiness; prefer to be lying down; fighting sleep; woozy |
| 7 almost in reverie; sleep onset soon; losing struggle to remain awake |
| Third Trial/Time: sleepy3 |
| 1 feeling active and vital; alert; wide awake |
| 2 could function at a high level, but not quite at peak; able to concentrate |
| 3 relaxed, awake, responsive, but not at full alertness |
| 4 a little foggy, not at peak, let down |
| 5 fogginess, beginning to lose interest in staying awake; slowed down |
| 6 sleepiness; prefer to be lying down; fighting sleep; woozy |
| 7 almost in reverie; sleep onset soon; losing struggle to remain awake |
| Fourth Trial/Time: sleepy4 |

| 1 feeling active and vital; alert; wide awake |
|--|
| 2 could function at a high level, but not quite at peak; able to concentrate |
| 3 relaxed, awake, responsive, but not at full alertness |
| 4 a little foggy, not at peak, let down |
| 5 fogginess, beginning to lose interest in staying awake; slowed down |
| 6 sleepiness; prefer to be lying down; fighting sleep; woozy |
| 7 almost in reverie; sleep onset soon; losing struggle to remain awake |
| |
| Fifth Trial/Time:sleepy5 |
| 1 feeling active and vital; alert; wide awake |
| 2 could function at a high level, but not quite at peak; able to concentrate |
| 3 relaxed, awake, responsive, but not at full alertness |
| 4 a little foggy, not at peak, let down |
| 5 fogginess, beginning to lose interest in staying awake; slowed down |
| 6 sleepiness; prefer to be lying down; fighting sleep; woozy |
| 7 almost in reverie; sleep onset soon; losing struggle to remain awake |
| |
| During the day today did you take any over-the-counter or prescription drugs? YES NO (mslt_drugs_yn) |
| If yes, please list the name of each one: (available upon request) |

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D) MSLT Technician Data Sheet

| Multiple Sleep La | itency Test-Da | ta sheet (TABLI | E: MSLT) | | | |
|-------------------|-------------------|---|---------------------|--------------------|--|---------------------------------|
| Those items in R | ED are only ga | thered during a | clinical MSLT) | | | |
| D#SUBJ_ID | | | Recorde | Recorded by: | | |
| Date:MSLT_D | ATE | | | Scorers: | | |
| CLINICAL_MSLT { | = Y if clinical N | ISLT, = N if rese | arch MSLT} | | | |
| | | | • • • | • • | pproximately two hou of the following occur | r intervals. For each nap, : |
| 1) 15 mir | nutes after the | 1st epoch of slo | eep (clinical); or; | | | |
| 1) 3 epoc | chs of continuo | ous stage 1 or 1 | epoch of any oth | er sleep stage (re | search); or; | |
| 2) the en | d of minute 20 |), even if no sle | ep occurred. | | | |
| Nap time | • | atency sleep onset) <u>Scorer 2</u> | Latency to REM | Epoch# | Did volunteer report sleep? (If yes, how long to sleep onset?) | |
| nap1_time | nap1_sl1 | nap1_sl2 | nap1_rem | not entered | nap1_sleep (Y/N) | |
| nap2_time | nap2_sl1 | nap2_sl2 | nap2_rem | not entered | nap2_sleep (Y/N) | |
| nap3_time | nap3_sl1 | nap3_sl2 | nap3_rem | not entered | nap3_sleep (Y/N) | |
| nap4_time | nap4_sl1 | nap4_sl2 | nap4_rem | not entered | nap4_sleep (Y/N) | |
| nap5_time | nap5_sl5 | nap5_sl2 | nap5_rem | not entered | nap5_sleep (Y/N) | |
| (If during nap | o1-nap4 there | is no occurrenc | e of a latency to I | REM, nap5 will no | t be conducted) | |
| | Sum of Sle | ep Latencies: | | | | |
| | Mean SI | eep Latency: | | | | |
| | Data c | onfirmed by: | | | | |
| Comments: _ | | | | | | |
| (The followin | g items in REC | were only gath | nered during a cli | nical MSLT.) | | |
| Nap1 | 1 | Nap2 | Nap3 | Nap4 | Nap5 | |

Indicate Y or N

Smoked cigarettes?

nap1_smoke_yn nap2_smoke_yn nap3_smoke_yn nap4_smoke_yn nap5_smoke_yn

If yes, enter time:

nap1_smoke_time nap2_smoke_time nap3_smoke_time nap4_smoke_time nap5_smoke_time nap1_smoke_time2 nap2_smoke_time2 nap3_smoke_time2 nap4_smoke_time2 nap5_smoke_time2 nap1_smoke_time3 nap2_smoke_time3 nap3_smoke_time3 nap4_smoke_time3 nap5_smoke_time3 nap5_smoke_time4 nap1_smoke_time4 nap2_smoke_time4 nap3_smoke_time4 nap4_smoke_time4

Drank caffeine?

nap1_caffeine_yn nap2_caffeine_yn nap3_caffeine_yn nap4_caffeine_yn nap5_caffeine_yn

If yes, enter #cups:

nap1_caffeine_cups nap2_caffeine_cups nap3_caffeine_cups nap4_caffeine_cups nap5_caffeine_cups

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