PRE-VISIT PREPARATION

VISIT TYPE: **VISIT 1 – (Week -2) Screening Visit**

FASTING STATUS: **N/A**

INVESTIGATIONAL PRODUCT DISPENSING: **NO**

CLINIC STAFF			
Name	**Initial**	**Signature**	**Date (DD-MMM-YYYY)**

VISIT TABLE CONTENTS

INFORMED CONSENT DOCUMENTATION
Version 1.2

- Greet Subject and bring back to private area.
- Explain Study:

"The purpose of this study is to determine the effect of the CELE1000 Study Product on sleep quality.

"This study will recruit 75 subjects, ages ≥ 25 and ≤ 75 years of age, which will be enrolled to receive 10 weeks supply of the study product."

"This consent is required before we begin any procedures. It will tell you all about the study and your obligations including qualifications, number of visits, and compensation."

- Hand subject the consent form on a clipboard with a highlighter:

"Please do not sign anything until I return. Highlight any areas you have questions about. To ensure that you understand what you've read, I will ask you questions about the number and type of visits, any possible side effects, and placebos."

"Before I leave can I get your initials?

SUBJECT INITIALS: ☐☐☐

Set Timer for 20 minutes. Record time and take timer with you. (hh:mm)

Start Time: ☐☐:☐☐ End Time: ☐☐:☐☐

After 20 minutes come back and ask if the subject needs more time. If yes, record 2nd start and end time. (hh:mm)

Start Time: ☐☐:☐☐ End Time: ☐☐:☐☐

- While the subject is reviewing the Informed Consent, get the screening log and record the subject's information in the Screening Log Binder on the next available line. The number to the left is the Screening Number. This will become the subject's identification and how the subject will be tracked throughout the study.

Please record Subject Screening Number in footer of every page of these CRF documents.

"Do you have any questions about this consent document or about the study?" ❑Yes[1] ❑No[2]

(Please record any questions asked):

Questions	Response Provided

- Ensure all questions are answered satisfactorily.
- Ask the following questions and record the answers:

Question	Subject Response	Correct Answer
"How long is the study?"		10 weeks
"Who should you call if you have a study-related emergency?"		Investigator
"How many visits are required to complete the study?"		6 visits

- Ask subject to initial all pages and sign and date at the signature tabs.
- Verify that all initials/signatures are in place.
- Countersign consent document.
- Obtain Investigator's signature on consent document.
- Make one copy of the fully executed, signed consent document and give one copy to the subject – place the original in the subject binder in the ICD section.

I certify the subject states he/she has read the consent form and has been given the opportunity to ask questions which, if any, have been answered to the best of our ability. Subject states awareness of potential risks and benefits of this study.

No study procedures will be performed until the ICD is fully executed

_____
Clinic Staff Printed Name

× _____ _____
Clinic Staff Signature *Date (DD-MMM-YYYY)*

_____
Investigator Printed Name

× _____ _____
Investigator Signature *Date (DD-MMM-YYYY)*

DEMOGRAPHIC DATA
Version 1.1

SUBJECT DEMOGRAPHICS

Birth date: (dd-mmm-yyyy):	Relationship Status	Sex:
	❑ Single[1] ❑ Married[2] ❑ Divorced[3] ❑ Separated[4] ❑ Widowed[5] ❑ Domestic Partner[6]	❑ Male[1] ❑ Female[2]

Ethnicity:

❑Latino/ Hispanic[1] ❑African-American[3] ❑Native American[5] ❑Hawaiian/Pacific Islander[7]
❑Asian[2] ❑Caucasian[4] ❑Alaska Native[6] ❑Other:[8] _____

MEDICUS RESEARCH

INCLUSION / EXCLUSION CRITERIA

Version 1.3

*INCLUSION CRITERIA		
Subjects with occasional insomnia.	Y☐[1]	N☐[2]
Subjects experiencing middle of the night awakenings with difficulty falling back to sleep at least 2 times per week.	Y☐[1]	N☐[2]
Sleep Quality Scale Score o TBD	Y☐[1]	N☐[2]
Healthy volunteers ≥ 25 and ≤ 75 years of age.	Y☐[1]	N☐[2]
Body mass index (BMI) ≥ 18 and ≤ 35 kg/m2.	Y☐[1]	N☐[2]
Judged by the Investigator to be in general good health on the basis of medical history.	Y☐[1]	N☐[2]
Females of child bearing potential must agree to use appropriate birth control methods during the entire study period.	Y☐[1]	N☐[2]
Agree not to initiate any new exercise or diet programs during the entire study period.	Y☐[1]	N☐[2]
Agree not to change their current diet or exercise program during the entire study period.	Y☐[1]	N☐[2]
Understands the study procedures and signs forms providing informed consent to participate in the study and authorization for release of relevant protected health information to the study investigator.	Y☐[1]	N☐[2]

*EXCLUSION CRITERIA			
Females who are lactating or who are pregnant.	N/A ☐[3]	Y☐[1]	N☐[2]
Night shift workers and individuals who nap 3 or more times per week over the preceding month.		Y☐[1]	N☐[2]
Consumption of caffeine-containing beverages (i.e. tea, coffee, energy drinks, or cola) comprising usually more than 5 cups or glasses per day.		Y☐[1]	N☐[2]
Participation in another trial having received study medication within one month before the screening visit.		Y☐[1]	N☐[2]
Use of any over-the-counter products including but not limited to the following (a two-week washout of these products is permitted): o Tryptophan, Valerian root (Valeriana officinialis), kava (Piper methysticum Forst), melatonin, St. John's Wort (Hypericum perforatum), Unisom (doxylamine succinate), Benadryl (diphenylhydramine), Tylenol PM (diphenylhydramine), Alluna (herbal supplement with valerian root) or prescription sleep medication, including hypnotics and sedatives, and anxiolytics, within one week or five half-lives (whichever is longer), prior to screening.		Y☐[1]	N☐[2]
Use of any substance with psychotropic effects or properties known to affect sleep/wake cycle, including, but limited to the following (a two-week washout of these products is permitted): o Neuroleptics, morphine/opioid derivatives, sedative antihistamines, stimulants, antidepressants, clonidine, within one week or five half-lives (whichever is longer), prior to screening.		Y☐[1]	N☐[2]
Patients unable to complete the study questionnaires.		Y☐[1]	N☐[2]
Patients unwilling to provide written, signed and dated informed consent must not be included in the study.		Y☐[1]	N☐[2]
Patients who are unable to demonstrate ability to use actimeter.		Y☐[1]	N☐[2]
Patients who are unable to participate for the entire duration of the study, or in the opinion of the investigator, are likely to be non-compliant with the obligations inherent in the trial participation.		Y☐[1]	N☐[2]
History of (i) primary hypersomnia, (ii) narcolepsy, (iii) breathing-related sleep disorder, (iv) circadian rhythm sleep disorder, (v) parasomnia (e.g. somnambulism), (vi) dyssomnia not otherwise specified, i.e., periodic leg movement syndrome.		Y☐[1]	N☐[2]
Patients with poorly controlled diabetes; i.e., a history of hospitalization for ketoacidosis within the past 12 months.		Y☐[1]	N☐[2]
Patients presenting with acute or chronic pain resulting in insomnia.		Y☐[1]	N☐[2]
Patients with current psychiatric disturbances according to DSM IV criteria including but not limited to psychosis and/or bipolar disorder, eating disorder, alcohol or substance abuse or dependence, or a history of lifetime psychosis and/or bipolar disorder.		Y☐[1]	N☐[2]
Patients with mental retardation or dementia.		Y☐[1]	N☐[2]
Patients with a history of epilepsy or seizures (not including benign neonatal and childhood convulsions).		Y☐[1]	N☐[2]
Evidence of any clinically significant, severe or unstable, acute or chronically progressive medical or surgical disorder, or any condition that may interfere with the absorption, metabolism, distribution or excretion of the study drug, or may affect patient safety.		Y☐[1]	N☐[2]
Serious head injury or stroke within the past year.		Y☐[1]	N☐[2]
Abnormal Physical Examination		Y☐[1]	N☐[2]
Subjects unable to understand or follow the study protocol		Y☐[1]	N☐[2]

***If any of the Inclusion criteria is marked "No" or any of the exclusion criteria is marked " Yes" say, "Thank you very much for your time. Unfortunately, you do not qualify for this particular study."**

Do you plan on relocating within the next 10 weeks? ❑Yes[1]❑No[2]	Do you plan on taking a vacation within the next 10 weeks? ❑Yes[1]❑No[2] If yes, how long?_____

If subject is not able to attend all study visits, they will NOT be able to participate in the study.

MEDICATION HISTORY

Version 1.3

Ask Subject

"Are you currently taking any medications including prescription, over the counter, dietary supplements, herbs or vitamins?" ❑Y[1] ❑N[2] If yes, list below and fill out the concomitant medication form:

Medication Name		Dosage / Units	Frequency (QD, QOD, BID, TID, qhs, etc.)	Reason (Indication)	Date Started (DD-MMM-YYY)	Date Ended (DD-MMM-YYY)
	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				
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	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				
	❑Brand ❑Generic	/				

PROHIBITED CONCOMITANT MEDICATIONS

Version 1.2

"Are you taking any of the following anticoagulant medications or dietary supplements?"
❑Yes[1] ❑No[2] If yes, check the box(es) below:

- ❑ **Alluna** (herbal supplement with valerian root)
- ❑ **Ambien** (Zolpidem)
- ❑ **Amitriptyline** (Elavil)
- ❑ **Antidepressants**
- ❑ **Ativan** (Lorazepam)
- ❑ **Benadryl** (diphenylhydramine)
- ❑ **Clonidine**
- ❑ **Dalmane** (Flurazepam)
- ❑ **Doral** (Quazepam)
- ❑ **Doxepin** (Sinequan)
- ❑ **Halcion** (Triazolam)
- ❑ **Kava** (Piper MethysticumForst)
- ❑ **Klonopin** (Clonazepam)
- ❑ **Lunesta** (Eszopiclone, formerly known as Estorra)
- ❑ **Melatonin**
- ❑ **Morphine/opioid derivatives**
- ❑ **Neuroleptics**
- ❑ **ProSom** (Estazolam)
- ❑ **Restoril** (Temazepam)
- ❑ **Rozerem**
- ❑ **Sedative antihistamines**
- ❑ **Sonata** (Zaleplon)
- ❑ **St. John's Wort** (Hypericum perforatum)
- ❑ **Stimulants**
- ❑ **Trazodone** (Desyrel),
- ❑ **Tryptophan**
- ❑ **Unisom** (doxylamine succinate)
- ❑ **Valerian Root** (Valerianaofficinalis)
- ❑ **Xanax** (Alprazolam)

If yes, do you agree to stop taking these products for the entire study? ❑Yes[1] ❑No[2]
Two weeks washout required.

If no, subject is a screen fail. Please stop here.

Date of last dose: | | | | | | | | | |

(D D – M M M – Y Y Y Y)

STUDY SPECIFIC ALLERGY
Version 1.2

"Are you allergic to any dietary foods?" ❑Yes[1] ❑No[2]

If yes, please specify:

_____

_____

MEDICATION ALLERGIES
Version 1.2

"Are you allergic to any medications including prescription, over the counter, dietary supplements, herbs, or vitamins?" ❑Yes[1] ❑No[2] If yes, list below:

Name of Medication		Dosage	Reaction	Date of Last Dose / Reaction (DD-MMM-YYY)
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			
	❑Brand ❑Generic			

FAMILY MEDICAL HISTORY
Version 1.2

"Does any member of your immediate family have,or ever had, any of the following medical problems?"

❑ Unknown medical history (adopted, other _____)

CONDITION	YES[1]	NO[2]	If yes, who? (Relationship to you)			
Vascular Disease	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle
Heart Disease	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle
Inflammatory Bowel Disease	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle
Cancer _____	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle
Hepatitis	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle
Other _____	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle
Other _____	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle
Other _____	❑	❑	❑Mother ❑Sibling	❑Father ❑Child	❑Grandmother ❑Aunt	❑Grandfather ❑Uncle

SOCIAL HISTORY
Version 1.2

"Do you have children?" ❑Y[1] ❑N[2]
"If yes, how many?" _____

"Do you currently work?" ❑Y[1] ❑N[2]
"If yes, what is your occupation?"_____

"Do you have any special dietary restrictions?" ❑Y[1] ❑N[2]
"If yes, explain:"_____

"Do you use tobacco products?" ❑Y[1] ❑N[2] ❑In the past[3]

(M M M – Y Y Y Y)

"If In the past, how long ago did you stop?" | | | | | | | |

TYPE	AMOUNT PER WEEK
Cigars	
Cigarettes	
Pipes	
Roll your own	
Snuff (oral, plugs, loose-leaf, nasal)	
Chewing tobacco	
Hookah (water pipes), Sisha, Charcoal	
Bidis (Wrapped in tendu or temburini leaves)	
Marijuana	

"Do you consume alcoholic beverages?" ❑Y[1] ❑N[2] ❑In the past[3]
"What kind of alcohol?" _____
"If yes, how many servings per week?" _____ **SERVING: 1 drink = 12 oz. beer = 5 oz. wine or 1 ½ ounces**
"At what age did you start?"
"If In the past, when did you stop?" | | | | | | | |
(M M M – Y Y Y Y)

"Do you have a drug dependency or do you abuse drugs?" ❑Y[1] ❑N[2] ❑In the past[3]
"If yes, which drugs?" _____

"If In the past, how long ago did you stop?" | | | | | | | |
(M M M – Y Y Y Y)

PROCEDURES – VITAL SIGNS
Version 1.3

Please take Subject's Vital Signs:

- Allow the subject to sit for 5 minutes.
- Take the measurement with the subject sitting, with legs uncrossed, in front of them.
- The cuff should be placed on the subject's dominant arm at heart level, back and arm should be supported. Please ask the subject to stay very still during measurement.

	RANGE:	NORMAL RANGE	OUT OF RANGE		CLINICALLY SIGNIFICANT (Only if out of range)	
TEMP:	☐☐☐.☐ °F	97.8° - 99.1°	❑ YES[1]	❑ NO[2]	❑ YES[1]	❑ NO[2]
BP:	☐☐☐ SBP	90-139	❑ YES[1]	❑ NO[2]	❑ YES[1]	❑ NO[2]
	☐☐☐ DBP	60-89	❑ YES[1]	❑ NO[2]	❑ YES[1]	❑ NO[2]
If subject with high blood pressure indicates chest pain, dizziness, headache, numbness and/or tingling in arms or legs, ALERT CLINICIAN. If subject with high blood pressure denies all of the above, there is NO NEED to alert clinician.						
PULSE:	☐☐☐ bpm	60-80	❑ YES[1]	❑ NO[2]	❑ YES[1]	❑ NO[2]
RESPIRATORY RATE:	☐☐ bpm	12-18	❑ YES[1]	❑ NO[2]	❑ YES[1]	❑ NO[2]

PROCEDURES – ANTHROPOMETRIC MEASURES

Please ask subject to remove their shoes and jacket before measuring Height and Weight.

WEIGHT: ☐☐☐.☐ lbs HEIGHT: ☐☐☐.☐ inches BMI: ☐☐.☐

Height should be measured using the stadiometer

Incl	**Is BMI ≥ 18 and ≤ 35?*(Must be Yes)***	❑Y[1]	❑N[2]

BIRTH CONTROL METHODS

Version 1.2

Read the following to the subject:

" Because it is not known whether the product in this study can affect an unborn child, you or your partner should not become pregnant while on this study. You and your partner should use a medically approved method of birth control while you are participating in this study. Approved forms of birth control are:"

❑oral contraceptives	❑injectable contraceptives
❑birth control patch	❑diaphragms
❑condoms	❑sponges
❑implantable contraceptives	❑cervical caps
❑vasectomy	❑tubal ligation
❑IUDs	❑vaginal ring

❑ The subject completed and signed the Agreement to Abstain From Sexual Intercourse form.

I understand that it is unknown if the study product may harm my unborn child if I or my partner becomes pregnant after I begin taking the study product.

Subject's Initials ☐☐☐

I agree to use an approved method of birth control as defined above, if or when, I am ever sexually active.

Subject's Initials ☐☐☐

(Please check the box(es) above to identify which method you agree to use.)

"My partner and I do not need to practice any of the above forms of birth control because:"

Subject's Initials ☐☐☐

- ❑ Either my partner or I have had a hysterectomy.
- ❑ Either my partner or I have been post-menopausal for > 2 years.

For official use only

❑ I certify that thecompleted Agreement to Abstain From Sexual Intercourse form was filed at the back of the Informed Consent Document.

CLINIC STAFF INITIALS ☐☐☐

SPECIMEN COLLECTION

Version 1.2

Body Fluid/Matrix: Urine

Date (dd-mmm-yyyy)	N/A	Actual Time (24 hour clock)	Unique Sample ID	Comments (Keep brief and legible)
	❑ (1)	:	(Urine Pregnancy Test) N/A ☐	

PROCEDURES – URINE PREGNANCY TEST
Version 1.3

REQUIRED:❑Yes[1]❑No[2]

If No, then check one reason:

❑ Male[1]❑ Post-Menopausal Female[2]❑Surgically Sterilized Female[3]

RESULT:❑POSITIVE[1]❑NEGATIVE[2]

If positive, repeat test

↓

RESULT OF REPEAT TEST: ❑POSITIVE[1]❑NEGATIVE[2]

If repeat test is positive, stop and do not proceed with screening visit!

DATE OF LAST MENSTRUAL PERIOD: | | | | | | | | |

(D D – M M M – Y Y Y Y)

Have you had unprotected sex since Your last menstrual period?❑Yes[1]❑No[2]
If yes, when? | | | | | | | | |

(D D – M M M – Y Y Y Y)

CRC URINE COLLECTION INSTRUCTIONS

1. Hand the subject a urine collection cup.
2. Instruct the subject to follow urine collection instructions posted in the restroom.
3. Instruct the subject to return the cup TO YOU when finished, and not leave it in the restroom.
4. Start processing the urine as soon as it is returned to you.

URINE PREGNANCY PROCESSING

1. Wearing gloves, accept the urine specimen (must have at least 3 ml of urine).
2. PRINT the subject's initials and identification number on the specimen container.
3. Open the pregnancy Kit. Kit will contain 1 clear pipette and 1 urine pregnancy cassette.
4. PRINT the subject's initials and identification number on the urine pregnancy cassette BEFORE testing.
5. Open the urine cup and with the clear pipette, pipette three drops into the circle indicated in the pregnancy cassette.
6. Once 3 drops of urine have been dropped, start the timer for 3 minutes.
7. After 3 minutes the result will be either a cross for positive or a straight line for negative.
8. Record result above.
9. Discard cassette into biohazard trash can (not sharps container) when finished.

QUESTIONNAIRE

The following questionnaire will be administered in this visit:

- ❑ **Sleep Questionnaire**

Please hand the QUESTIONNAIRE on the next pages to the subject.

SLEEP QUESTIONNAIRE

Version 1.2

This questionnaire is for patients 13 years of age. It will take approximately 15 to 20 minutes to complete. The information you provide is very important and will assist the sleep specialist during the review of your sleep symptoms. This questionnaire has been compiled based on many years of accumulated experience in Sleep Medicine. Please respond to all questions by checking the appropriate box or completing the free text sections.

SLEEP SCHEDULE

1.	What time do you go to bed on **weekdays**?	_____ ❑ a.m. ❑ p.m.
2.	What time do you go to bed on **weekends**?	_____ ❑ a.m. ❑ p.m.
3.	What time do you get out of bed on **weekdays**?	_____ ❑ a.m. ❑ p.m.
4.	What time do you get out of bed on **weekends**?	_____ ❑ a.m. ❑ p.m.
5.	How much sleep do you get on an average night (hours)?	_____
6.	Are you a morning type, evening type, neither:	❑Morning type ❑Evening type ❑Neither
7.	What would be your ideal bedtimes? (**from** (a.m./p.m.) **to** (a.m./p.m.))	_____
8.	Do you nap?	❑ Yes ❑ No
9.	How often do you nap? (number of times per week)	_____
10.	How long are the naps? (in minutes)	_____
11.	Do you awaken refreshed from the nap?	❑ Yes ❑ No
12.	What are your usual work hours?	_____
13.	Are you a shift worker?	❑ Yes ❑ No
	If yes, what kind of shift do you work (hours)?	_____
14.	What is (was) your occupation?	_____
	If retired, when?	_____

SLEEP HISTORY

1.	Do you have difficulty falling asleep?	❑ Yes	❑ No
2.	Do you have difficulty staying asleep?	❑ Yes	❑ No
3.	Do you wake up too early and cannot get back to sleep?	❑ Yes	❑ No
4.	Do you have thoughts racing through your mind that make it difficult to sleep?	❑ Yes	❑ No
5.	How long does it take you to fall asleep at night (minutes)?	_____	
6.	Do you read in bed?	❑ Yes	❑ No
7.	Do you watch TV in bed?	❑ Yes	❑ No
8.	Do you share the bed with anyone?	❑ Yes	❑ No
9.	Does your partner have a sleep disorder?	❑ Yes	❑ No
10.	Do you have pets sleep in the bedroom?	❑ Yes	❑ No
11.	Is your bedroom comfortable?	❑ Yes	❑ No
	If yes, please describe:	_____	
		_____	
12.	How many times do you wake up during the night?	_____	

13.	How long does it take you to fall asleep again (minutes)?	_____	
14.	Do you have unpleasant feelings of fear, anxiety, tension, or unhappiness waking you up?	❑ Yes	❑ No
15.	Do you have feelings of muscle tension or tightness in your arms or chest?	❑ Yes	❑ No
16.	Do you have pain or joint discomfort?	❑ Yes	❑ No
17.	Do you have other problems waking you up?	❑ Yes	❑ No
	If yes, please describe: _____		
18.	In the morning, do you wake up with an alarm, naturally, both:	❑ With an alam ❑ Naturally	❑ Both
19.	In the morning, do you wake up feeling sleepy, groggy, refreshed, tired:	❑ Sleepy ❑Groggy ❑Refreshed	❑ Tired

ABNORMAL MOVEMENT/BEHAVIORS

	› you have or have you ever experienced:	❑ Yes	❑ No
1.	An urge to move your legs, usually accompanied by uncomfortable and unpleasant sensations in the legs?	❑ Yes	❑ No
2.	Discomfort in the legs that worsen during periods of rest or inactivity such as laying down or sitting?	❑ Yes	❑ No
3.	Discomfort in the legs that is relieved by movement: walking or stretching?	❑ Yes	❑ No
4.	Discomfort that worsens during the nighttime?	❑ Yes	❑ No
5.	Do you have leg cramps (Charley horse)?	❑ Yes	❑ No
6.	Do you kick or jerk your arms or legs during sleep?	❑ Yes	❑ No
7.	Are your bed covers messy in the morning?	❑ Yes	❑ No
8.	Do you kick, punch, or poke your bed partner while asleep?	❑ Yes	❑ No
	If yes, have you ever injured your bed partner or yourself?	❑ Yes	❑ No
9.	Do you grind your teeth?	❑ Yes	❑ No
10.	Do you wear a bite splint (mouth guard)?	❑ Yes	❑ No
11.	Do you walk in your sleep?	❑ Yes	❑ No
	If yes, when was the last time?	_____	
12.	Do you talk in your sleep?	❑ Yes	❑ No
13.	Do you have nightmares or night terrors?	❑ Yes	❑ No
	If yes, please describe the behavior, including the time of night, and frequency: _____		
14.	Have you acted out your dreams?	❑ Yes	❑ No
15.	Do you make rolling movements or bang and twist your head at night?	❑ Yes	❑ No
16.	Have you had sleep problems as a child?	❑ Yes	❑ No
	If yes, please describe: _____		

DAYTIME SLEEPINESS

1.	Have you fallen asleep unexpectedly?	❑ Yes	❑ No
2.	Have you ever had an accident or near-miss because you have	❑ Yes	❑ No

fallen asleep while driving?

If **yes**, when? _____

3. Have you **ever** experienced sudden muscle weakness when you laugh, listen to a joke, are surprised or angry? ❑ Yes ❑ No

If **yes, during** your episode of muscle weakness. If no, please skip to the next question

a) Can you hear? ❑ Yes ❑ No
b) Does your speech ever become slurred? ❑ Yes ❑ No
c) Is your head affected? ❑ Yes ❑ No
d) Is your whole body affected? ❑ Yes ❑ No
e) How long does the weakness usually last? _____

4. Have you experienced dreamlike images or sounds while falling asleep or waking up? ❑ Yes ❑ No
5. Have you experienced an inability to move while falling asleep or waking up? ❑ Yes ❑ No

THE EPWORTH SLEEPINESS SCALE

How likely are to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation:

0 = would never doze, 1 = slight chance of dozing, 2 = moderate chance of dozing, 3 = high chance of dozing

1. Sitting and reading _____
2. Watching TV _____
3. Sitting, inactive in a public place (e.g. a theatre or meeting) _____
4. As a passenger in a car for an hour without a break _____
5. Lying down to rest in the afternoon when circumstances permit _____
6. Sitting and talking to someone _____
7. Sitting quietly after a lunch without alcohol _____
8. In a car, while stopped for a few minutes in the traffic _____

Total score out of 24: ☐

SNORING/BREATHING HISTORY

1. Do you snore? _____
2. What is your preferred sleep position (% of the time in each)?
   a) Back (% of sleep time) _____% of sleep time
   b) Left Side (% of sleep time) _____% of sleep time
   c) Right Side (% of sleep time) _____% of sleep time
   d) Stomach (% of sleep time) _____% of sleep time
3. Does your sleep position affect your snoring? ❑ Yes ❑ No
4. Do you awaken with a snort, choking or gasping for air? ❑ Yes ❑ No
5. Do you awaken with a headache? ❑ Yes ❑ No
6. Has anyone noticed you stop breathing while asleep? ❑ Yes ❑ No
7. Do you awaken often to urinate during the night? ❑ Yes ❑ No
8. Do you awaken with acid or sour taste in your mouth? ❑ Yes ❑ No
9. Do you have difficulty breathing while on your back? ❑ Yes ❑ No
10. Do you avoid sharing a room because of snoring? ❑ Yes ❑ No
11. Do you sweat excessively during the night? ❑ Yes ❑ No
12. Do you awaken with a dry mouth or sore throat? ❑ Yes ❑ No

MEDICAL HISTORY-HEALTH PROBLEMS

Version 1.5

☐NONE

CONDITION / ILLNESS	DATE OF ONSET (DD-MMM-YYYY)	DATE OF RESOLUTION (OR ONGOING) (DD-MMM-YYYY)	TREATMENT / THERAPIES

REVIEW OF SYSTEMS

Version 1.1

When reviewing each system, please check "No" if there are no problems within that system. Please mark "Yes" if there are ANY problems within that system. If "Yes", please CIRCLE the specific area.

❑Yes[1] ❑No[2]	**IMMUNE HEALTH**	AIDS, HIV, Ankylosing Spondylitis, Chronic Fatigue Syndrome, CREST syndrome, Crohn's disease, Dermatomyositis, Fibromyalgia, Grave's disease, Hashimoto's Thyroiditis, Lupus, Multiple Sclerosis, Myasthenia Gravis, Pernicious Anemia, PolyarteritisNodosa, Primary Biliary Cirrhosis, Psoriasis, Reynaud's Syndrome, Rheumatoid Arthritis, Sarcoidosis, Scleroderma, Sjogren's Syndrome, Temporal Arthritis, Ulcerative Colitis, and Vitiligo, Other _____
❑Yes[1] ❑No[2]	**NEUROLOGIC**	Seizures, dizziness, numbness/tingling in arms/legs, Diabetic Neuropathy, fainting spells, stroke, headaches (migraine, sinus, tension), Other _____
❑Yes[1] ❑No[2]	**EYES**	Nearsighted (myopia), farsighted (hyperopia), reading glasses (presbyopia), blurred vision, glaucoma, cataracts, retina problems, blindness, implanted contacts, Other _____
❑Yes[1] ❑No[2]	**EARS**	Ringing in ears (tinnitus), hearing loss, frequent ear infections, increased ear wax (cerumen) production, Other _____
❑Yes[1] ❑No[2]	**NOSE**	Nasal congestion, chronic allergies, sinus problems, nose bleeds, post nasal drip, deviated septum. Other _____
❑Yes[1] ❑No[2]	**THROAT/MOUTH**	Trouble swallowing, frequent tonsil infections, dry mouth, scratchy/sore throat**,** mouth sores. Other _____
❑Yes[1] ❑No[2]	**HEMATOPOETIC/ LYMPHATIC/ ONCOLOGIC**	Blood disorders, low red blood cell counts (anemia), low white blood cell counts (leucopenia), low platelets, swollen glands, bleeding problems, blood transfusions, cancer:_____ Other _____
❑Yes[1] ❑No[2]	**RESPIRATORY**	Asthma, emphysema (COPD), chronic cough, tuberculosis, shortness of breath, chronic bronchitis.
❑Yes[1] ❑No[2]	**CARDIOVASCULAR**	Chest pain, high blood pressure, heart attack, hardening of the arteries (arteriosclerosis), irregular heartbeat, slow pulse, pacemaker, blood clots, varicose veins, rheumatic fever, and increased cholesterol. Other _____
❑Yes[1] ❑No[2]	**GASTROINTESTINAL**	Ulcer-(Stomach/Gastric/Duodenal), heartburn, nausea/vomiting, acid reflux, Abdominal bloating/cramps, constipation, diarrhea, irritable bowel syndrome/spastic colon, gallbladder problems or stones, pancreas problems, ulcerative colitis, diverticulosis, diverticulitis, hemorrhoids, bleeding in the stomach or intestines, blood in the stool, black or tarry stools, Other _____
❑Yes[1] ❑No[2]	**HEPATIC**	Jaundice, hepatitis A, B or C, history of abnormal liver function tests, cirrhosis (Do not document hepatitis vaccinations), Other _____
❑Yes[1] ❑No[2]	**ENDOCRINE/ METABOLIC**	Low blood sugar (Hypoglycemia), High blood sugar (Hyperglycemia),thyroid problems, Diabetes (hyperthyroid/hypothyroid), Overweight (BMI: 25-29.9), obesity (BMI>30), Other _____
❑Yes[1] ❑No[2]	**RENAL/ GENITOURINARY**	Kidney problems, Kidney stones, frequent Urinary infections, problems with reproductive organs **If Male:** Prostate, Other _____
❑Yes[1] ❑No[2]	**IF FEMALE**	Fibrocystic breast disease, uterine fibroid, ovarian cyst, perimenopausal, postmenopausal Other _____
❑Yes[1] ❑No[2]	**MUSCULOSKELETAL**	Fibromyalgia, broken bones, osteoarthritis, rheumatoid arthritis**,** osteoporosis, back pain, leg cramps, gout, Other _____
❑Yes[1] ❑No[2]	**DERMATOLOGICAL**	Eczema, shingles, hives, rashes, psoriasis, dry skin, acne, impetigo, vitiligo, Other _____
❑Yes[1] ❑No[2]	**PSYCHIATRIC**	Anxiety, depression, fatigue, drowsiness, insomnia, psychosis, hospitalization for psychiatric illness, Other _____
❑Yes[1] ❑No[2]	**SURGERIES**	Have any of the following organs removed? ❑Gallbladder[1]❑Tonsils[2]❑Appendix[3]❑Uterus[4]❑Ovaries[5] **If Female:** Have you had a child by c-section? ❑Yes[1]❑No[2]

PHYSICAL EXAMINATION

Version 1.4

	Within Normal Limits	Abnormal	N/A	Description if abnormal or significant finding
General appearance No acute distress, Able to speak in full sentences	☐	☐NCS ☐CS	☐	
Eyes, ears, nose and throat Pupils equal reactive to light and accommodation, Anicteric Sclera, NOSE – normal, Oropharynx – clear, no exudates, no erythema, SINUSES- no sinus tenderness, EARS – within normal limits including tympanic membranes.	☐	☐NCS ☐CS	☐	
Cardiovascular Regular rate and rhythm, Normal S1 and S2 NO S3, S4, Murmurs, Rubs, or Gallops	☐	☐NCS ☐CS	☐	
Respiratory Clear to auscultation bilaterally, no wheezes, ronchi or rales	☐	☐NCS ☐CS	☐	
Neurologic Alert and Oriented X3	☐	☐NCS ☐CS	☐	
Lymphatic No Lymphadenopathy	☐	☐NCS ☐CS	☐	
Gatrointestinal Normal active bowel sounds, no rebound guarding, or tenderness	☐	☐NCS ☐CS	☐	
Genitourinary	☐	☐NCS ☐CS	☐	
Skin No rashes, discoloration or growths	☐	☐NCS ☐CS	☐	
Other: _____	☐	☐NCS ☐CS	☐	

INVESTIGATOR INITIALS	*Date (DD-MMM-YYYY)*

INVESTIGATOR ASSESSMENT

Version 1.2

Please review subject's Medical History (from this visit) and Screening I/E Questions. Please provide any additional comments/ questions you feel are necessary. If none are necessary, please check "No further questions necessary".

❑No further questions necessary

Note to Investigator: General medical conditions that are well-controlled will not be a basis for exclusion in the study. Subjects with conditions that are not adequately controlled or that might pose an unacceptable risk for participation as clinically determined by the investigator will be excluded.

Subjects that have unstable medical, psychiatric or substance abuse disorders, that in the opinion of the investigator, are likely to affect the subject's ability to complete the study or precludes the subject's participation in the study will be excluded.

X

CLINICIAN SIGNATURE ***DATE** (DD-MMM-YYYY)*

SCHEDULE FORM
Version 1.2

Make sure subject is aware they will be receiving phone calls in between visits and ask for their preferred phone number where they would like to be contacted. Please record below.

SITE ID	V1 SCREENING DATE (DD-MMM-YYYY)	CLINIC STAFF INITIALS
1001		

SCREENING NUMBER	SUBJECT INITIALS

VISIT	SCHEDULED DATE	SCHEDULED TIME
V2 VISIT (2 WEEKS AFTER V1)		☐ AM ☐ PM
V2.5 COMPLIANCE CALL		❑MORNING ❑AFTERNOON ❑EVENING
V3 VISIT (3 WEEKS AFTER V2)		☐ AM ☐ PM
V3.5 COMPLIANCE CALL		❑MORNING ❑AFTERNOON ❑EVENING
V4 VISIT (1 WEEK AFTER V3)		☐ AM ☐ PM
V4.5 COMPLIANCE CALL		❑MORNING ❑AFTERNOON ❑EVENING
V5 VISIT (3 WEEKS AFTER V4)		☐ AM ☐ PM
V5.5 COMPLIANCE CALL		❑MORNING ❑AFTERNOON ❑EVENING
V6 VISIT (1 WEEK AFTER V5)		☐ AM ☐ PM

DISPENSING PROCEDURES

Version 1.1

INVESTIGATIONAL STUDY PRODUCT	None
RESCUE MEDICATION	None
DIARIES	Stanford Sleepiness Scale
STANDARDIZED FOOD	None
PROCEDURE EQUIPMENT	Actigraphy Unit
HOME SPECIMEN COLLECTION KITS	None

FUNDS ACKNOWLEDGEMENT
Version 1.2

My signature below is to acknowledge receipt of $10.00 today. I understand that this sum will be deducted from my total compensation amount.

✖ _____ _____
Subject's Signature Date (DD-MMM-YYYY)

I have issued $10.00 to the subject mentioned above. I have explained that this sum will be deducted from their total compensation amount.

_____
Clinic Staff Printed Name

✖ _____ _____
Clinic Staff Signature Date (DD-MMM-YYYY)

STIPEND PAYMENT
Version 1.1

VISIT	DATE OF VISIT	AMOUNT DESIGNATED FOR V1	VISIT COMPLETED	$10.00STIPEND DISBURSED:
V1		**$25**	❑ Yes[1] ❑ No[2]	❑ Yes[1] ❑ No[2]

CHECKOUT
Version 1.1

- ☐ Informed Consent Documentation
- ☐ Demographic Data
- ☐ Inclusion/Exclusion Criteria
- ☐ Medication History
- ☐ Prohibited Concomitant Medications
- ☐ Study Specific Allergy
- ☐ Medication Allergies
- ☐ Family Medical History
- ☐ Social History
- ☐ Vital Signs
- ☐ Birth Control Methods
- ☐ Procedures
- ☐ Specimen Collection
- ☐ Urine Pregnancy Test
- ☐ Questionnaire
  - Sleep Questionnaire
- ☐ Medical History
  - Medical History-Health Problems
- ☐ Review of Systems
- ☐ Physical Examination Form
- ☐ Investigator Assessment
- ☐ Schedule Form
- ☐ Funds Acknowledgement
- ☐ Stipend Payment
- ☐ Checkout
- ☐ Investigator Process Acknowledgement
- ☐ Stanford Sleepiness Scale
- ☐ Handout -Subject Study Expectations

MEDICUS RESEARCH

INVESTIGATOR PROCESS ACKNOWLEDGEMENT

Version 1.1

VISIT NOTES: ❑Yes[1] ❑No[2]

(specific to a procedure that was not completed or anything that happened during the visit that was out of the ordinary)

INVESTIGATOR INITIALS

Date (DD-MMM-YYYY)

STANFORD SLEEPINESS SCALE

Version 1.2

Instruction: Answer this scale **hourly** from the time of waking up in the morning until noon.

Screening Number: _____

Date: | | | | | | | | |

(DD-MMM-YYYY)

Wake-up Time: | | | : | | |

Wake-up Time Stanford Rating: | |

The scale comprises of a 1 to 7 rating, as shown below. Pick what **best** represents how you're feeling and note the number.

Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not at peak; able to concentrate	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dream-like thoughts	7
Asleep	X

Stanford Rating: | | **05:00**

Stanford Rating: | | **06 : 00**

Stanford Rating: | | **07 : 00**

Stanford Rating: | | **08 : 00**

Stanford Rating: | | **09 : 00**

Stanford Rating: | | **10 : 00**

Stanford Rating: | | **11 : 00**

Stanford Rating: | | **12 : 00**

HANDOUT – SUBJECT STUDY EXPECTATIONS

Version 1.4

NEXT VISIT	Your next visit is ☐☐☐☐☐☐☐☐☐ (DD-MMM-YYYY) at ☐☐☐☐ ☐ AM ☐ PM
STUDY DIARIES	Please complete the Stanford Sleepiness Scale every morning when you wake up.
STUDY PRODUCT	There is NO study product for this visit.
CONCOMITANT MEDICATIONS	The following medications or dietary supplements are prohibited during this study: ❑ **Alluna** (herbal supplement with valerian root) ❑ **Ambien** (Zolpidem) ❑ **Amitriptyline** (Elavil) ❑ **Antidepressants** ❑ **Ativan** (Lorazepam) ❑ **Benadryl** (diphenylhydramine) ❑ **Clonidine** ❑ **Dalmane** (Flurazepam) ❑ **Doral** (Quazepam) ❑ **Doxepin** (Sinequan) ❑ **Halcion** (Triazolam) ❑ **Kava** (Piper MethysticumForst) ❑ **Klonopin** (Clonazepam) ❑ **Lunesta** (Eszopiclone, formerly known as Estorra) ❑ **Melatonin** ❑ **Morphine/opioid derivatives** ❑ **Neuroleptics** ❑ **ProSom** (Estazolam) ❑ **Restoril** (Temazepam) ❑ **Rozerem** ❑ **Sedative antihistamines** ❑ **Sonata** (Zaleplon) ❑ **St. John's Wort** (Hypericum perforatum) ❑ **Stimulants** ❑ **Trazodone** (Desyrel), ❑ **Tryptophan** ❑ **Unisom** (doxylamine succinate) ❑ **Valerian Root** (Valerianaofficinalis) ❑ **Xanax** (Alprazolam)
RESCUE MEDICATION	There is NO rescue medication for this study.
EXPECTATIONS	1. If you are sexually active and you or your partner are of child-bearing potential, please use appropriate birth control throughout the entire study. 2. Don't change your diet during the study. 3. Don't change your exercise routine (or start a new exercise routine) during the study.
STANDARDIZED FOOD	There is NO standardized food dispensed for this visit
FASTING INSTRUCTIONS	You do NOT need to fast before your next visit. Do NOT consume any **coffee, tea, enery drinks** or any other **caffeinated** beverages after 4PM on a daily basis. Do NOT consume any alcoholic beverage after 7PM (Sunday – Thursday)
SLEEP INSTRUCTIONS	Please get your normal amount of sleep the night before your next visit.
AT HOME SPECIMEN COLLECTION	There are **NO** specimens to be collected at home for this study
CONTACT	Our 24 hour phone number is 866-407-0266

STUDY	Site	SCREENING NUMBER	DATA CODES
CELE1000	**1001**		Refused=7 Not Applicable=8 Missing/Not Collected=9