

PRE-NIELSEN TEST INFORMATION FORM

ID No.		-			
Form Type	N	A			

This form is to be completed by the Research Coordinator after the patient has dressed in standard clothing but before the Nielsen Test starts.

Part I: Visit Identification

- Patient's initials: -----
- Date of Nielsen Test: ----- Feb-DAYS
Month Day Year
- Visit at which this Nielsen Test is being performed: ----- VIS_NUM
- Time the patient arrived in the test site building: ----- ARRHR ARRMMN
Hours Minutes
Military Time
- Outside temperature at the time the patient entered the building (nearest whole degree C; circle either + or -): ----- SIGN (+) TEMP 1 °C (-)

Part II: Diet/Smoking/Medication Record

- Hours since the end of the patient's last meal: ----- LAST MEAL
- If response to Item 6 is less than two, reschedule the Nielsen Test.
- Did this meal conform to the restrictions given to the patient before the test? ----- MEAL
(1) (2)
Yes No

A. What aspect of the meal did not conform to the restrictions. (Check all that apply.)

(1) Meal was too heavy ----- (1)

(2) Meal contained too much fat -- (1)

(3) Meal contained caffeine ----- (1)

(4) Meal contained alcohol ----- (1)

HEAVY
FAT
CAFF
ALCOH

ID No.		-			
Form Type	N	A			

8. Has the patient ingested coffee containing caffeine within the last two hours? ----- (1) (2)
 Yes No

Coff 24

Reschedule the Nielsen Test.

9. Has the patient ingested a soft drink containing caffeine within the last two hours? ----- (1) (2)
 Yes No

Soft 24

Reschedule the Nielsen Test.

10. Has the patient ingested any alcohol in the last 24 hours? ----- (1) (2)
 Yes No

ALCOH 24

Reschedule the Nielsen Test.

11. Has the patient taken any prescription medications (other than RTS study medication) in the last 24 hours? ----- (1) (2)
 Yes No

PRESC 24

	(1) Medication	(2) Hours Since Last Taken
A.	<i>MED A</i>	-----
B.	<i>MED B</i>	-----
C.	<i>MED C</i>	-----

If any of these medications are disqualifying medications (see list used at screening) reschedule the test. Contact the patient's physician to determine if the medications are required for a present condition or if the patient can discontinue medication for at least one month. If the medication is required and cannot be discontinued contact the Principal Investigator to determine if the study medication should be stopped. Please do not unblind the treatment to make this determination. Reschedule the test even if the patient must take the listed medication.

If the patient can discontinue the medication, reschedule the test for a date at least one month after the patient stops taking the medication.

ID No.		-			
Form Type	N	A			

12. Has the patient taken any non-prescription medications in the last 24 hours? ----- (1) (2) *NON 24*
 Yes No

If the medication has a vasodilation effect, reschedule the Nielsen Test.

13. Does the patient currently smoke cigarettes? ----- (1) (2) *CURRSMK*
 Yes No

A. How many cigarettes does the patient usually smoke per day? ----- *NUMSMK*
 B. Has the patient smoked a cigarette within the last two hours? ----- (1) (2) *SMOKE-24*
 Yes No
 ↓
 Reschedule the Nielsen Test.

14. Time the patient changed into standard test clothing: ----- *CHHR* : *CHMN*
 Hours Minutes
 (Military Time)

15. Temperature of outer room at start of equilibration period (nearest 0.5° C): ----- *TEMP2* ° C

16. Did the patient engage in any treatment procedures (take study medication, practice biofeedback exercises) in the last 48 hours? ----- (1) (2) *TRE 48*
 Yes No

17. Has the patient been reminded not to discuss treatment assignment or prior treatment sessions with the Nielsen technician? ----- (1) (2) *REMIND*
 Yes No

Part III: Administrative Matters

18. Research Coordinator:
 Signature: _____ RTS Staff No.: _____

19. Date form completed: -----
 Month Day Year

ID No.		-			
Form Type	N	A			

ID No.		-			
Form Type	N	A			

This form is to be completed by the Research Coordinator after the patient has dressed in standard clothing but before the Nielsen Test starts.

Part I: Visit Identification

1. Patient's initials:
2. Date of Nielsen Test: FL-DAYS
 Month Day Year
3. Visit at which this Nielsen Test is being performed: VIS-NUM
4. Time the patient arrived in the test site building: ARRHR: ARRMIN
 Hours Minutes
 Military Time
5. Outside temperature at the time the patient entered the building (nearest whole degree C): TEMP °C

Part II: Diet/Smoking/Medication Record

6. Hours since the end of the patient's last meal: LASTMEAL

If response to Item 6 is less than two, reschedule the Nielsen Test.

7. Did this meal conform to the restrictions given to the patient before the test? MEAL
 () ()
 Yes No

A. What aspect of the meal did not conform to the restrictions. (Check all that apply.)

(1) Meal was too heavy () HEAVY
 (2) Meal contained too much fat -- () FAT
 (3) Meal contained caffeine () CAFF
 (4) Meal contained alcohol () ALCH

ID No.		-			
Form Type	N	A			

8. Has the patient ingested coffee containing caffeine within the last two hours? () ()
 Yes No

Coffee

Reschedule the Nielsen Test.

9. Has the patient ingested a soft drink containing caffeine within the last two hours? () ()
 Yes No

SODA

Reschedule the Nielsen Test.

10. Has the patient ingested any alcohol in the last 24 hours? () ()
 Yes No

ALCOHOL

Reschedule the Nielsen Test.

11. Has the patient taken any prescription medications (other than RTS study medication) in the last 24 hours? () ()
 Yes No

PRESC.

	(1) Medication	(2) Hours Since Last Taken
A.	MED A	-----
B.	MED B	-----
C.	MED C	-----

If any of these medications are disqualifying medications (see list used at screening) reschedule the test. Contact the patient's physician to determine if the medications are required for a present condition or if the patient can discontinue medication for at least one month. If the medication is required and cannot be discontinued contact the Principal Investigator to determine if the study medication should be stopped. Please do not unblind the treatment to make this determination. Reschedule the test even if the patient must take the listed medication.

If the patient can discontinue the medication, reschedule the test for a date at least one month after the patient stops taking the medication.

ID No.		-			
Form Type	N	A			

12. Has the patient taken any non-prescription medications
 in the last 24 hours? (1) (2)
 Yes No

If the medication has a vasodilation effect, reschedule the Nielsen Test.

13. Does the patient currently smoke cigarettes? (1) (2)
 Yes No

A. How many cigarettes does the patient usually smoke per day?

B. Has the patient smoked a cigarette within the last two hours? (1) (2)
 Yes No

Reschedule the Nielsen Test.

14. Time the patient changed into standard test clothing: ---- : ----
 Hours Minutes
 (Military Time)

15. Temperature of outer room at start of equilibration period (nearest 0.5° C): ° C

16. Did the patient engage in any treatment procedures (take study medication, practice biofeedback exercises) in the last 48 hours? (1) (2)
 Yes No

17. Has the patient been reminded not to discuss treatment assignment or prior treatment sessions with the Nielsen technician? (1) (2)
 Yes No

Part III: Administrative Matters

18. Research Coordinator:
 Signature: RTS Staff No.:

19. Date form completed:
 Month Day Year

ID No.		-			
Form Type	N	A			

PRE-NIELSEN TEST INFORMATION FORM

ID No.		-			
Form Type	N	A			

This form is to be completed by the Research Coordinator after the patient has dressed in standard clothing but before the Nielsen Test starts.

Part I: Visit Identification

1. Patient's initials: -----
2. Date of Nielsen Test: ----- FL-DAYS
Month Day Year
3. Visit at which this Nielsen Test is being performed: ----- VIS-NUM
4. Time the patient arrived in the test site building: ----- ARRHR : ARRMN
Hours Minutes
Military Time
5. Outside temperature at the time the patient entered the building (nearest whole degree C): ----- TEMP °C

Part II: Diet/Smoking/Medication Record

6. Hours since the end of the patient's last meal: ----- LASTMEAL

If response to Item 5 is less than two, reschedule the Nielsen Test.

7. Did this meal conform to the restrictions given to the patient before the test? ----- MEAL
(1) (2)
Yes No
↓

A. What aspect of the meal did not conform to the restrictions. (Check all that apply.)

(1) Meal was too heavy ----- (1)

(2) Meal contained too much fat -- (1)

(3) Meal contained caffeine ----- (1)

(4) Meal contained alcohol ----- (1)

*HEAVY
FAT
CAFF
ALCH*

ID No.		-			
Form Type	N	A			

8. Has the patient ingested coffee containing caffeine within the last two hours? ----- (1) (2)
 Yes No

Coffee

Reschedule the Nielsen Test.

9. Has the patient ingested a soft drink containing caffeine within the last two hours? ----- (1) (2)
 Yes No

Soft-drink

Reschedule the Nielsen Test.

10. Has the patient ingested any alcohol in the last 24 hours? ----- (1) (2)
 Yes No

Alcohol

Reschedule the Nielsen Test.

11. Has the patient taken any prescription medications in the last 24 hours? ----- (1) (2)
 Yes No

PRESC-24

	(1) Medication	(2) Hours Since Last Taken
A.	<i>MEDA</i>	___
B.	<i>MEOB</i>	___
C.	<i>MEOC</i>	___

12. Has the patient taken any non-prescription medications in the last 24 hours? ----- (1) (2)
 Yes No

NON-24

Reschedule the Nielsen Test.

ID No.		-			
Form Type	N	A			

CURRSMK

13. Does the patient currently smoke cigarettes? ----- (1) (2)
Yes No



A. How many cigarettes does the patient usually smoke per day? -----	<u>Num Smk</u>
B. Has the patient smoked a cigarette within the last two hours? -----	<u>Smoke-24</u> (1) (2) Yes No
↓	
Reschedule the Nielsen Test.	

14. Time the patient changed into standard test clothing: ----- CHHR : CHMN
Hours Minutes
(Military Time)

15. Temperature of outer room at start of equilibration period (nearest 0.5° C): ----- TEMP 2 ° C

16. Did the patient engage in any treatment procedures (take study medication, practice biofeedback exercises) in the last 48 hours? ----- TRT-48
(1) (2)
Yes No

17. Has the patient been reminded not to discuss treatment assignment or prior treatment sessions with the Nielsen technician? ----- REMIN
(1) (2)
Yes No

Part III: Administrative Matters

18. Research Coordinator:
Signature: _____ RTS Staff No.: _____

19. Date form completed: -----
Month Day Year

ID No.		-			
Form Type	N	A			

NIELSEN TEST FORM

ID No.		-			
Form Type	N	B			

Part I: Visit Identification

1. Patient's initials:

2. Date of Nielsen Test: Flg-DAYS
Month Day Year

3. Visit at which this Nielsen Test is being performed: Vis. NUM

4. Date of last water bath calibration: BTH-DAYS
Month Day Year

5. Date of last finger temperature probe calibration: TMP-DAYS
Month Day Year

6. Has the procedure been explained to the patient and the patient advised of his/her right to discontinue? RIGHTS
() ()
Yes No

Part II: Administration of Nielsen Test

7. Temperature of outer room at end of equilibration period (nearest 0.5°C): NTEMP1 °C

8. Time of entry into 20°C room ENHR : ENMIN
Hours Minutes
Military Time

9. Temperature of test chamber at start of equilibration period (nearest 0.1°C): NTEMP2 °C

10. Hand tested (dominant hand should be used for test): HANDTEST
() ()
Right Left

11. Finger tested (middle finger should be used): FINGTEST
() () ()
Index Middle Ring

ID No.		-			
Form Type	N	B			

12. Finger Systolic Pressure Check

Target Number	(1)	(2)
	Manometer Reading	Digital Computer Readout
A. 1000	MANA1000 mm Hg	DIGA1000 mm Hg
B. 500	MANA500 mm Hg	DIGA500 mm Hg
C. 250	MANA250 mm Hg	DIGA250 mm Hg

13. Patient's manual arm blood pressure:

A. Systolic MANA SYS mm Hg
 B. Diastolic MANEDIA mm Hg

14. Patient's first arm blood pressure from the Nielsen equipment:

A. Systolic NIELA SYS mm Hg
 B. Diastolic NIELB DIA mm Hg

15. Finger systolic blood pressure at the following temperatures:

		(1)		(2)
		Did Artery Reopen?		Pressure
		Yes	No*	
NOPEN 30	A. 30°C	()	()	NPRESS 30 A mm Hg
NOPEN 20	B. 20°C	()	()	NPRESS 20 B mm Hg
NOPEN 15	C. 15°C	()	()	NPRESS 15 C mm Hg
NOPEN 10	D. 10°C	()	()	NPRESS 10 D mm Hg

*If artery did not reopen at any given temperature, skip column (2) for that temperature and columns (1) and (2) for all lower temperatures.

ID No.				
Form Type	N	B		

NABORT

16. Was the test aborted? (1) (2)
 Yes No

A. Temperature at which test was aborted: NTEMP3 °C

B. Was the test aborted because of the zero re-opening pressure? - (1) (2) NZERO
 Yes No

(1) Time between zero cuff pressure and return of pulse: NZCMIN NZCSEC
 Minutes Seconds

(2) Pulse returned: NPULSE

Spontaneously (1)

Within 20 seconds of blood pressure measurement (2)

After warming the hand with a hair dryer (3)

17. Test chamber temperature at end of test (nearest 0.1°C): NTEMP4 °C

18. Were there any problems (other than aborting the test because of zero re-opening pressure) in administering this test? (1) (2)
 Yes No

OT# PRO6

A. Specify: OT# PRO6

ID No.		-			
Form Type	N	B			

If the Stroop/Repeat Nielsen Test is performed, use the same finger as before; continue the procedure without "unhooking" the patient. If there was zero re-opening pressure in the first test, warm the hand (after the arm blood pressure reading) until the pulse returns.

STR. RPT

19. Was the Stroop/Repeat Nielsen Test done? () ()
 Yes No

Skip to Item 25. *23*

A. Which test was done?

TEST DONE

Stroop ()
 Repeat Nielsen ()

B. Was it necessary to warm the patient's hand prior to the start of the Stroop/Repeat Nielsen Test? () ()
 Yes No

WARM HAND

C. Starting time of Stroop/Repeat Nielsen Test: *STAR* : *STMN*
 Hours Minutes
 Military Time

20. Finger systolic blood pressure at the following temperatures:

		(1)		(2)	
		Did Artery Reopen?		Pressure	
		Yes	No*		
<i>ROPEN 30</i>	A. 30°C	()	()	<i>R PRESS 30A</i>	mm Hg
<i>ROPEN 20</i>	B. 20°C	()	()	<i>R PRESS 20A</i>	mm Hg
<i>ROPEN 15</i>	C. 15°C	()	()	<i>R PRESS 15C</i>	mm Hg
<i>ROPEN 10</i>	D. 10°C	()	()	<i>R PRESS 10D</i>	mm Hg

*If artery did not reopen at any given temperature, skip column (2) for that temperature and columns (1) and (2) for all lower temperatures.

ID No.		-			
Form Type	N	B			

21. Was the test aborted? (1) (2) **ABORT**
 Yes No
 ↓

A. Temperature at which test was aborted: **NTENPS** °C

B. Was the test aborted because of the zero re-opening pressure? (1) (2) **RZERO**
 Yes No
 ↓

(1) Time between zero cuff pressure and return of pulse: **RZCMM** **RZCSM**
 Minutes Seconds

(2) Pulse returned:

Spontaneously **RPUSE** (1)
 Within 20 seconds of blood pressure measurement (2)
 After warming the hand with a hair dryer (3)

22. Stopping time of Stroop/Repeat Nielsen Test: **STPHR** : **STPHM**
 Hours Minutes
 Military Time

Part III: Administrative Matters

23. Has the diskette of the Nielsen Test and Stroop/Repeat Nielsen Test (if done) been sent to the Coordinating Center? (1) (2) **NIELNSK**
 Yes No
 ↓

A. Date sent:
 Month Day Year

Please affix a label to the diskette and record the patient's I.D. Number, Initials and the Form Type of this form.

ID No.		-			
Form Type	N	B			

24. Nielsen Technician:

Signature: _____ RTS Staff No.: _____

25. Research Coordinator:

Signature: _____ RTS Staff No.: _____

26. Date form completed: _____
 Month Day Year

COORDINATING CENTER USE ONLY	
27. Diskette from the Nielsen Test received? -----	(1) (2) Yes No
↓	
A. Date received: -- _____ <div style="display: flex; justify-content: space-around; width: 100%;"> Month Day Year </div>	

ID No.					
Form Type	N	B			

NIELSEN TEST FORM

ID No.		-			
Form Type	N	B			

Part I: Visit Identification

- Patient's initials: ----- FL
- Date of Nielsen Test: ----- FL-DAYS
Month Day Year
- Visit at which this Nielsen Test is being performed: ----- VIS. NUM
- Date of last water bath calibration: ----- BTH-DAYS
Month Day Year
- Date of last finger temperature probe calibration: ----- TMP-DAYS
Month Day Year
- Has the procedure been explained to the patient and the patient advised of his/her right to discontinue? ----- RIGHTS
() ()
Yes No

Part III: Administration of Nielsen Test

- Temperature of outer room at end of equilibration period (nearest 0.5°C): ----- NTEMP1 °C
- Time of entry into 20°C room ----- ENHR ENMN
Hours Minutes
Military Time
- Temperature of test chamber at start of equilibration period (nearest 0.1°C): ----- NTEMP2 °C
- Hand tested (dominant hand should be used for test): ----- HANDTEST
() ()
Right Left
- Finger tested (middle finger should be used): ----- FINGTEST
() () ()
Index Middle Ring

ID No.		-			
Form Type	N	B			

12. Finger Systolic Pressure Check

Target Number	(1)		(2)	
	Manometer Reading		Digital Computer Readout	
A. 1000	<u>MAN1000</u>	mm Hg	<u>DIG1000</u>	mm Hg
B. 500	<u>MAN500</u>	mm Hg	<u>DIG500</u>	mm Hg
C. 250	<u>MAN250</u>	mm Hg	<u>DIG250</u>	mm Hg

13. Patient's manual arm blood pressure:

A. Systolic mm Hg
 B. Diastolic mm Hg

MANSYS
MANDIAS

14. Patient's first arm blood pressure from the Nielsen equipment:

A. Systolic mm Hg
 B. Diastolic mm Hg

NIENSYS
NIENDIAS

15. Finger systolic blood pressure at the following temperatures:

		(1)		(2)	
		Did Artery Reopen?		Pressure	
		Yes	No*		
<i>NO OPEN 30</i>	A. 30°C	()	()	<u>NPRESS30</u>	mm Hg
<i>NO OPEN 20</i>	B. 20°C	()	()	<u>NPRESS20</u>	mm Hg
<i>NO OPEN 15</i>	C. 15°C	()	()	<u>NPRESS15</u>	mm Hg
<i>NO OPEN 10</i>	D. 10°C	()	()	<u>NPRESS10</u>	mm Hg

*If artery did not reopen at any given temperature, skip column (2) for that temperature.

ID No.				
Form Type	N	B		

16. Was the test aborted? (1) (2) *ABORT 3*
 Yes No
 ↓

A. Temperature at which test was aborted: *NTEMP* °C

B. Was the test aborted because of the zero re-opening pressure? - (1) (2) *ZERO*
 Yes No
 ↓

(1) Time between zero cuff pressure and return of pulse: *NZDMN* : *NZLSEC*
 Minutes Seconds

(2) Pulse returned: *NPU* SE

Spontaneously (1)

Within 20 seconds of blood pressure measurement (2)

After warming the hand with a hair dryer (3)

17. Test chamber temperature at end of test (nearest 0.1°C): *NTEMP* °C

18. Were there any problems (other than aborting the test because of zero re-opening pressure) in administering this test? (1) (2) *OTHER PROB*
 Yes No
 ↓

A. Specify: *OTHER PROB*

19. Has the diskette of the Nielsen Test been sent to the Coordinating Center? (1) (2) *NIELSENT*
 Yes No
 ↓

A. Date sent:

 Month Day Year

B. Names of files: (1) _____
 (2) _____
 (3) _____
 (4) _____

ID No.				
Form Type	N	B		

If the Stroop/Repeat Nielsen Test is performed, use the same finger as before; continue the procedure without "unhooking" the patient. If there was zero re-opening pressure in the first test, warm the hand (after the arm blood pressure reading) until the pulse returns.

STROOP

20. Was the Stroop/Repeat Nielsen Test done? ----- () ()
Yes No

TEST DONE

Skip to Item 25.

A. Which test was done?

Stroop ----- ()
Repeat Nielsen ----- ()

WARM HAND

B. Was it necessary to warm the patient's hand prior to the start of the Stroop/Repeat Nielsen Test? ----- () ()
Yes No

C. Starting time of Stroop/Repeat Nielsen Test: *.57* : *31*
Hours Minutes
Military Time

21. Finger systolic blood pressure at the following temperatures:

(1)

(2)

Did Artery Reopen?

Pressure

REOPEN 30
REOPEN 20
REOPEN 15
REOPEN 10

	(1)		(2)	
	Yes	No*	Pressure	
A. 30°C	()	()	<u><i>R PRESS 30</i></u>	mm Hg
B. 20°C	()	()	<u><i>R PRESS 20</i></u>	mm Hg
C. 15°C	()	()	<u><i>R PRESS 15</i></u>	mm Hg
D. 10°C	()	()	<u><i>R PRESS 10</i></u>	mm Hg

*If artery did not reopen at any given temperature, skip column (2) for that temperature.

ID No.				
Form Type	N	B		

22. Was the test aborted? RABORT (1) (2)
 Yes No
 ↓

A. Temperature at which test was aborted: NTEMP5 °C

B. Was the test aborted because of the zero re-opening pressure? - (1) (2) RZERO
 Yes No
 ↓

(1) Time between zero cuff pressure and return of pulse: RZEMIN : RZCSEC
 Minutes Seconds

(2) Pulse returned:
 Spontaneously RPULSE (1)
 Within 20 seconds of blood pressure measurement (2)
 After warming the hand with a hair dryer (3)

23. Stopping time of Stroop/Repeat Nielsen Test: STPHR : STPMN
 Hours Minutes
 Military Time

24. Has the diskette of the Stroop/Repeat Nielsen Test been sent to the Coordinating Center? STRPSENT (1) (2)
 Yes No
 ↓

A. Date sent: _____
 Month Day Year

B. Names of files: (1) _____
 (2) _____
 (3) _____
 (4) _____

ID No.				
Form Type	N	B		

Part III: Administrative Matters

25. Nielsen Technician:

Signature: _____ RTS Staff No.: _____

26. Research Coordinator:

Signature: _____ RTS Staff No.: _____

27. Date form completed: _____

Month Day Year

COORDINATING CENTER USE ONLY	
28. Diskette from the Nielsen Test received? -----	(1) (2) Yes No ↓
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> A. Date received: -- ___ ___ - ___ ___ - ___ ___ Month Day Year </div>	
29. Diskette from the Stroop/Repeat Nielsen Test received? -----	(1) (2) Yes No ↓
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> A. Date received: -- ___ ___ - ___ ___ - ___ ___ Month Day Year </div>	

ID No.					
Form Type	N	B			

FORM 6A (Rev. 0, 1, 2)

PRE-NIELSEN TEST INFORMATION FORM

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID*	I(4)	Patient ID
HEADER	FMTYPA	CHAR(4)	NA01, NA02, NA03
2	F6_DAYS	I(4)	Date of Nielsen test Days from randomization
3	VIS_NUM	CHAR(4)	RV01, FV02, FV04
4	ARRHR	I(2)	Hours (Military time)
4	ARRMN	I(2)	Minutes
5	TEMP1	I(3)	°C
6	LASTMEAL	I(2)	Hours
7	MEAL	}	1 = Yes, 2 = No
7A1	HEAVY		
7A2	FAT		
7A3	CAFF		
7A4	ALCH		
8	COFF_24	I(1)	1 = Yes, 2 = No
9	SODA_24	I(1)	1 = Yes, 2 = No
10	ALCH_24	I(1)	1 = Yes, 2 = No
11	PRESC_24	I(1)	1 = Yes, 2 = No
11A	MEDA	}	1 = Remark written on form
11B	MEDB		
11C	MEDC		
12	NON_24	I(1)	1 = Yes, 2 = No
13	CURRSMK	I(1)	1 = Yes, 2 = No
13A	NUMSMK	I(3)	Cigarettes per day
13B	SMOKE_24	I(1)	1 = Yes, 2 = No
14	CHHR	I(2)	Hours (Military time)
14	CHMN	I(2)	Minutes
15	TEMP2	F(4.1)	°C
16	TRT_48	I(1)	1 = Yes, 2 = No
17	REMIND	I(1)	1 = Yes, 2 = No

* Persons in the Normal Substudy will have ID numbers 557-608. These persons are not in the randomization file or any other RTS file.

FORM 6B (Rev. 0, 1)*

NIELSEN TEST FORM

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID**	I(4)	Patient ID
HEADER	FMTYPB	CHAR(4)	NB01, NB02, NB03
2	F6_DAYS	I(4)	Date of Nielsen test Days from randomization
3	VIS_NUM	CHAR(4)	RV01, FV02, FV04
4	BTH_DAYS	I(4)	Days rand. to last water bath calibration
5	TMP_DAYS	I(4)	Days rand. to last finger probe calibration
6	RIGHTS	I(1)	1 = Yes, 2 = No
7	NTEMP1	F(4.1)	°C
8	ENHR ENMN	I(2) I(2)	Hours (Military time) Minutes
9	NTEMP2	F(4.1)	°C
10	HANDTEST	I(1)	1 = Right, 2 = Left
11	FINGTEST	I(1)	1 = Index 2 = Middle 3 = Ring
12A1 12B1 12C1 12A2 12B2 12C2	MAN1000 MAN500 MAN250 DIG1000 DIG500 DIG250	} } I(3)	mm Hg
13A 13B	MANSYS MANDIAS	I(3) I(3)	mm Hg mm Hg
14A 14B	NIELSYS NIELDIAS	I(3) I(3)	mm Hg mm Hg
15A1 15B1 15C1 15D1	NOPEN30 NOPEN20 NOPEN15 NOPEN10	} } I(1)	1 = Yes, 2 = No
15A2 15B2 15C2 15D2	NPRESS30 NPRESS20 NPRESS15 NPRESS10	} } I(3)	mm Hg

* Except where indicated by (Rev 0) Item numbers are from Rev 1.

** Persons in the normal Substudy will have ID numbers 557-608. These persons are not in the randomization file or any other RTS file.

FORM 6B (Rev. 0, 1)*

NIELSEN TEST FORM
(Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
16	NABORT	I(1)	1 = Yes, 2 = No
16A	NTEMP3	I(2)	°C
16B	NZERO	I(1)	1 = Yes, 2 = No
16B1	NZCMIN	I(2)	Minutes
16B1	NZCSEC	I(2)	Seconds
16B2	NPULSE	I(1)	1 = Spontaneously 2 = Within 20 seconds of blood pressure measurement 3 = After warming hand with hair dryer
17	NTEMP4	F(4.1)	°C
18	OTHRPROB	I(1)	1 = Yes, 2 = No
18A	OTHRRMK	CHAR(1)	1 = Remark written on form
19 (Rev 0)	NIELSENT	I(1)	1 = Yes, 2 = No
19	STR_RPT	I(1)	1 = Yes, 2 = No
19A	TESTDONE	I(1)	1 = Stroop 2 = Repeat Nielsen
19B	WARMHAND	I(1)	1 = Yes, 2 = No
19C	STHR	I(2)	Hours (Military Time)
	STMN	I(2)	Minutes
20A1	ROPEN30	}	1 = Yes, 2 = No
20B1	ROPEN20		
20C1	ROPEN15		
20D1	ROPEN10		
20A1	RPRESS30	}	mm Hg
20B1	RPRESS20		
20C1	RPRESS15		
20D1	RPRESS10		
21	RABORT	I(1)	1 = Yes, 2 = No
21A	NTEMP5	I(2)	°C
21B	RZERO	I(1)	1 = Yes, 2 = No
21B1	RZCMIN	I(2)	Minutes
21B1	RZCSEC	I(2)	Seconds
21B2	RPULSE	I(1)	1 = Spontaneously 2 = Within 20 seconds of blood pressure measurement 3 = After warming hand with hair dryer
22	STPHR	I(2)	Hours (Military Time)
	STPMN	I(2)	Minutes
23	NIELDISK	I(1)	1 = Yes, 2 = No
24 (Rev 0)	STRPSENT	I(1)	1 = Yes, 2 = No

* Except where indicated by (Rev 0) Item numbers are from Rev 1.

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM6A6B	Observations:	555
Member Type:	DATA	Variables:	90
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	380
Last Modified:	11:06 Thursday, April 27, 2000	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	11776
Number of Data Set Pages:	20
File Format:	607
First Data Page:	2
Max Obs per Page:	30
Obs in First Data Page:	30

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Informat	Label
ff							
10	ALCH	Num	4	36	1.	BEST22.	f6aq7a4 Meal contained alcohol
13	ALCH_24	Num	4	48	1.	BEST22.	f6aq10 Any alcohol within 24 hrs
2	ARRHR	Num	4	4	2.	BEST22.	f6aq4 Hour Patient arrived
3	ARRMN	Num	4	8	2.	BEST22.	f6aq4 Minute Patient arrived
89	BTH_DAYS	Num	8	364	4.		f6bq4 Days rand. to water bath calibrati
9	CAFF	Num	4	32	1.	BEST22.	f6aq7a3 Meal contained caffeine
22	CHHR	Num	4	75	2.	BEST22.	f6aq14 Hour patient changed clothes
23	CHMN	Num	4	79	2.	BEST22.	f6aq14 Minutes patient changed clothes
11	COFF_24	Num	4	40	1.	BEST22.	f6aq8 Coffee with caffeine within 2 hrs
19	CURRSMK	Num	4	63	1.	BEST22.	f6aq13 Patient currently smokes
40	DIG250	Num	4	159	3.	BEST22.	f6bq12c2 Digital SP check (250 mmHg)
39	DIG500	Num	4	155	3.	BEST22.	f6bq12b2 Digital SP check (500 mmHg)
38	DIG1000	Num	4	151	3.	BEST22.	f6bq12a2 Digital SP check (1000 mmHg)
30	ENHR	Num	4	115	2.	BEST22.	f6bq8 Time of entry (hour)
31	ENMN	Num	4	119	2.	BEST22.	f6bq8 Time of entry (minutes)
87	F6_DAYS	Num	4	352	4.		f06q2 Days from randomization
8	FAT	Num	4	28	1.	BEST22.	f6aq7a2 Meal contained too much fat
34	FINGTEST	Num	4	135	1.	BEST22.	f6bq11 Finger tested
27	FMTYPA	Char	4	99			Form 6A type
86	FMTYPB	Char	4	348			f6b Form 6B type
33	HANDTEST	Num	4	131	1.	BEST22.	f6bq10 Hand tested
7	HEAVY	Num	4	24	1.	BEST22.	f6aq7a1 Meal was too heavy
5	LASTMEAL	Num	4	16	2.	BEST22.	f6aq6 Hours since last meal
37	MAN250	Num	4	147	3.	BEST22.	f6bq12c1 Manometer SP check (250 mmHg)
36	MAN500	Num	4	143	3.	BEST22.	f6bq12b1 Manometer SP check (500 mmHg)
35	MAN1000	Num	4	139	3.	BEST22.	f6bq12a1 Manometer SP check (1000 mmHg)
42	MANDIAS	Num	4	167	3.	BEST22.	f6bq13b Manual DBP (mmHg)
41	MANSYS	Num	4	163	3.	BEST22.	f6bq13a Manual SBP (mmHg)
6	MEAL	Num	4	20	1.	BEST22.	f6aq7 Did meal conform to restrictions?
15	MEDA	Char	1	56			f6aq11a Prescription medication

13:16 Friday, April 28, 2000

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
16	MEDB	Char	1	57			f6aq11b Prescription medication
17	MEDC	Char	1	58			f6aq11c Prescription medication
53	NABORT	Num	4	211	1.	BEST22.	f6bq16 Test was aborted
88	NEWID	Num	8	356	4.		Patient ID
44	NIELDIAS	Num	4	175	3.	BEST22.	f6bq14b 1st Nielsen DBP (mmHg)
85	NIELDISK	Num	4	344	1.	BEST22.	f6bq23 Diskettes sent to CC
62	NIELSENT	Num	8	248	1.	BEST22.	f6bq19(rev0) Nielsen diskette sent to CC
43	NIELSYS	Num	4	171	3.	BEST22.	f6bq14a 1st Nielsen SPB (mmHg)
18	NON_24	Num	4	59	1.	BEST22.	f6aq12 Nonprescription med within 24 hrs
48	NOPEN10	Num	4	191	1.	BEST22.	f6bq15c1 Artery reopened at 10C
47	NOPEN15	Num	4	187	1.	BEST22.	f6bq15c1 Artery reopened at 15C
46	NOPEN20	Num	4	183	1.	BEST22.	f6bq15b1 Artery reopened at 20C
45	NOPEN30	Num	4	179	1.	BEST22.	f6bq15a1 Artery reopened at 30C
52	NPRESS10	Num	4	207	3.	BEST22.	f6bq15d2 Finger SBP at 10C
51	NPRESS15	Num	4	203	3.	BEST22.	f6bq15c2 Finger SBP at 15C
50	NPRESS20	Num	4	199	3.	BEST22.	f6bq15b2 Finger SBP at 20C
49	NPRESS30	Num	4	195	3.	BEST22.	f6bq15a2 Finger SBP at 30C
58	NPULSE	Num	4	231	1.	BEST22.	f6bq16b2 Pulse returned
29	NTEMP1	Num	8	107	4. 1	BEST22.	f6bq7 Room temp after equilibration (C)
32	NTEMP2	Num	8	123	4. 1	BEST22.	f6bq9 Starting test chamber temp (C)
54	NTEMP3	Num	4	215	2.	BEST22.	f6bq16a Temp when test was aborted (C)
59	NTEMP4	Num	8	235	4. 1	BEST22.	f6bq17 Ending test chamber temp (C)
77	NTEMP5	Num	4	312	2.	BEST22.	f6bq21a Temp when test was aborted (C)
20	NUMSMK	Num	4	67	3.	BEST22.	f6aq13a Cigarettes per day
56	NZCMN	Num	4	223	2.	BEST22.	f6bq16b1 Time to return of pulse (Min)
57	NZCSEC	Num	4	227	2.	BEST22.	f6bq16b1 Time to return of pulse (Sec)
55	NZERO	Num	4	219	1.	BEST22.	f6bq16b Zero reopening pressure
60	OTHRPROB	Num	4	243	1.	BEST22.	f6bq18 Any other problems
61	OTHRRMK	Char	1	247			f6bq18a Specify other problem
14	PRESC_24	Num	4	52	1.	BEST22.	f6aq11 Prescription med within 24 hrs
76	RABORT	Num	4	308	1.	BEST22.	f6bq21 Stroop/Repeat Nielsen was aborted
26	REMI ND	Num	4	95	1.	BEST22.	f6aq17 Reminded not to discuss treatment
28	RIGHTS	Num	4	103	1.	BEST22.	f6bq6 Patient advised of rights
71	ROPEN10	Num	4	288	1.	BEST22.	f6bq20d1 Artery reopened at 10C
70	ROPEN15	Num	4	284	1.	BEST22.	f6bq20c1 Artery reopened at 15C
69	ROPEN20	Num	4	280	1.	BEST22.	f6bq20b1 Artery reopened at 20C
68	ROPEN30	Num	4	276	1.	BEST22.	f6bq20a1 Artery reopened at 30C
75	RPRESS10	Num	4	304	3.	BEST22.	f6bq20d2 Finger SBP at 10C
74	RPRESS15	Num	4	300	3.	BEST22.	f6bq20c2 Finger SBP at 15C
73	RPRESS20	Num	4	296	3.	BEST22.	f6bq20b2 Finger SBP at 20C
72	RPRESS30	Num	4	292	3.	BEST22.	f6bq20a2 Finger SBP at 30C
81	RPULSE	Num	4	328	1.	BEST22.	f6bq21b2 Pulse returned
79	RZCMN	Num	4	320	2.	BEST22.	f6bq21b1 Time to return of pulse (min)
80	RZCSEC	Num	4	324	2.	BEST22.	f6bq21b1 Time to return of pulse (sec)
78	RZERO	Num	4	316	1.	BEST22.	f6bq21b Zero reopening pressure
21	SMOKE_24	Num	4	71	1.	BEST22.	f6aq13b Smoked within 24 hrs
12	SODA_24	Num	4	44	1.	BEST22.	f6aq9 Soda with caffeine within 2 hrs

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
fff							
66	STHR	Num	4	268	2.	BEST22.	f6bq19c Start time (hours)
67	STMN	Num	4	272	2.	BEST22.	f6bq19d Start time (min)
82	STPHR	Num	4	332	2.	BEST22.	f6bq22 Stroop/Rpt Nielsen stoptime (min)
83	STPMN	Num	4	336	2.	BEST22.	f6bq22 Stroop/Rpt Nielsen stoptime (sec)
84	STRPSENT	Num	4	340	1.	BEST22.	f6bq25(rev0) Stroop/RptNielsen disk sent
63	STR_RPT	Num	4	256	1.	BEST22.	f6bq19 Stroop/Repeat Nielsen test done
4	TEMP1	Num	4	12	3.	BEST22.	f6aq5 Outside temperature (C)
24	TEMP2	Num	8	83	4.1	BEST22.	f6aq15 Temperature of outer room (C)
64	TESTDONE	Num	4	260	1.	BEST22.	f6bq19a Which test was done
90	TMP_DAYS	Num	8	372	4.		f6bq5 Days rand. to finger probe calibra
25	TRT_48	Num	4	91	1.	BEST22.	f6aq16 Any treatments within 48 hrs
1	VIS_NUM	Char	4	0			f6q3 Visit Nielsen Test performed
65	WARMHAND	Num	4	264	1.	BEST22.	f6bq19b Hand warmed prior to test

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
ARRHR	f6aq4 Hour Patient arrived	553	11.2	2.8	1.0	19.0
ARRMN	f6aq4 Minute Patient arrived	552	24.0	19.8	0.0	59.0
TEMP1	f6aq5 Outside temperature (C)	550	11.4	9.8	-13.0	40.0
LASTMEAL	f6aq6 Hours since last meal	552	4.2	3.6	1.0	19.0
MEAL	f6aq7 Did meal conform to restrictions?	552	1.0	0.0	1.0	2.0
HEAVY	f6aq7a1 Meal was too heavy	552	2.0	0.0	2.0	2.0
FAT	f6aq7a2 Meal contained too much fat	552	2.0	0.0	2.0	2.0
CAFF	f6aq7a3 Meal contained caffeine	552	2.0	0.0	1.0	2.0
ALCH	f6aq7a4 Meal contained alcohol	552	2.0	0.0	2.0	2.0
COFF_24	f6aq8 Coffee with caffeine within 2 hrs	552	2.0	0.0	2.0	2.0
SODA_24	f6aq9 Soda with caffeine within 2 hrs	552	2.0	0.0	2.0	2.0
ALCH_24	f6aq10 Any alcohol within 24 hrs	552	2.0	0.1	1.0	2.0
PRESC_24	f6aq11 Prescription med within 24 hrs	551	1.7	0.5	1.0	2.0
NON_24	f6aq12 Nonprescription med within 24 hrs	551	1.9	0.2	1.0	2.0
CURRSMK	f6aq13 Patient currently smokes	552	1.9	0.3	1.0	2.0
NUMSMK	f6aq13a Cigarettes per day	58	16.5	9.9	1.0	40.0
SMOKE_24	f6aq13b Smoked within 24 hrs	58	2.0	0.0	2.0	2.0
CHHR	f6aq14 Hour patient changed clothes	553	11.3	2.7	1.0	19.0
CHMN	f6aq14 Minutes patient changed clothes	552	23.9	18.7	0.0	59.0
TEMP2	f6aq15 Temperature of outer room (C)	551	22.8	1.4	18.5	33.4
TRT_48	f6aq16 Any treatments within 48 hrs	552	1.5	0.5	1.0	2.0
REMIND	f6aq17 Reminded not to discuss treatment	552	1.2	0.4	1.0	2.0
RIGHTS	f6bq6 Patient advised of rights	552	1.0	0.0	1.0	1.0
NTEMP1	f6bq7 Room temp after equilibration (C)	552	23.0	1.1	20.0	28.0
ENHR	f6bq8 Time of entry (hour)	551	12.0	2.7	2.0	19.0
ENMN	f6bq8 Time of entry (minutes)	551	28.9	16.6	0.0	59.0
NTEMP2	f6bq9 Starting test chamber temp (C)	552	20.0	0.4	18.4	23.5
HANDTEST	f6bq10 Hand tested	549	1.1	0.3	1.0	2.0
FINGTEST	f6bq11 Finger tested	549	2.0	0.2	1.0	3.0
MAN1000	f6bq12a1 Manometer SP check (1000 mmHg)	550	241.8	4.9	142.0	245.0
MAN500	f6bq12b1 Manometer SP check (500 mmHg)	550	121.5	0.9	112.0	124.0
MAN250	f6bq12c1 Manometer SP check (250 mmHg)	550	60.7	1.0	58.0	63.0
DIG1000	f6bq12a2 Digital SP check (1000 mmHg)	550	242.3	5.1	141.0	247.0
DIG500	f6bq12b2 Digital SP check (500 mmHg)	550	121.6	1.0	112.0	124.0
DIG250	f6bq12c2 Digital SP check (250 mmHg)	550	60.4	1.1	57.0	63.0
MANSYS	f6bq13a Manual SBP (mmHg)	548	115.6	13.1	85.0	162.0
MANDIAS	f6bq13b Manual DBP (mmHg)	548	72.0	8.8	50.0	105.0
NIELSYS	f6bq14a 1st Nielsen SPB (mmHg)	542	120.2	14.5	90.0	188.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
NIELDIAS	f6bq14b 1st Nielsen DBP (mmHg)	542	69.7	11.1	43.0	107.0
NOPEN30	f6bq15a1 Artery reopened at 30C	541	1.0	0.1	1.0	2.0
NOPEN20	f6bq15b1 Artery reopened at 20C	528	1.1	0.3	1.0	2.0
NOPEN15	f6bq15c1 Artery reopened at 15C	463	1.4	0.5	1.0	2.0
NOPEN10	f6bq15c1 Artery reopened at 10C	276	1.3	0.4	1.0	2.0
NPRESS30	f6bq15a2 Finger SBP at 30C	528	100.5	31.8	1.0	204.0
NPRESS20	f6bq15b2 Finger SBP at 20C	470	102.3	31.1	1.0	179.0
NPRESS15	f6bq15c2 Finger SBP at 15C	280	93.3	38.5	0.0	205.0
NPRESS10	f6bq15d2 Finger SBP at 10C	200	89.2	38.8	0.0	201.0
NABORT	f6bq16 Test was aborted	536	1.3	0.5	1.0	2.0
NTEMP3	f6bq16a Temp when test was aborted (C)	348	15.4	4.4	10.0	30.0
NZERO	f6bq16b Zero reopening pressure	349	1.1	0.3	1.0	2.0
NZCMIN	f6bq16b1 Time to return of pulse (Min)	317	2.5	2.0	0.0	8.0
NZCSEC	f6bq16b1 Time to return of pulse (Sec)	317	22.7	18.1	0.0	59.0
NPULSE	f6bq16b2 Pulse returned	318	2.4	0.9	1.0	3.0
NTEMP4	f6bq17 Ending test chamber temp (C)	533	20.0	0.5	18.0	26.8
OTHRPROB	f6bq18 Any other problems	541	1.7	0.5	1.0	2.0
NIELSENT	f6bq19(rev0) Nielsen diskette sent to CC	30	1.1	0.3	1.0	2.0
STR_RPT	f6bq19 Stroop/Repeat Nielsen test done	552	1.7	0.5	1.0	2.0
TESTDONE	f6bq19a Which test was done	176	1.5	0.5	1.0	2.0
WARMHAND	f6bq19b Hand warmed prior to test	175	1.4	0.5	1.0	2.0
STHR	f6bq19c Start time (hours)	175	13.6	2.9	9.0	20.0
STMN	f6bq19d Start time (min)	175	26.2	17.3	0.0	59.0
ROPEN30	f6bq20a1 Artery reopened at 30C	176	1.0	0.2	1.0	2.0
ROPEN20	f6bq20b1 Artery reopened at 20C	169	1.0	0.2	1.0	2.0
ROPEN15	f6bq20c1 Artery reopened at 15C	157	1.4	1.0	1.0	8.0
ROPEN10	f6bq20d1 Artery reopened at 10C	108	1.3	0.4	1.0	2.0
RPRESS30	f6bq20a2 Finger SBP at 30C	171	107.2	32.4	1.0	219.0
RPRESS20	f6bq20b2 Finger SBP at 20C	158	105.3	32.5	1.0	188.0
RPRESS15	f6bq20c2 Finger SBP at 15C	114	95.1	40.1	0.0	205.0
RPRESS10	f6bq20d2 Finger SBP at 10C	81	82.4	43.7	0.0	174.0
RABORT	f6bq21 Stroop/Repeat Nielsen was aborted	176	1.5	0.5	1.0	2.0
NTEMP5	f6bq21a Temp when test was aborted (C)	95	15.3	5.2	10.0	30.0
RZERO	f6bq21b Zero reopening pressure	96	1.2	0.4	1.0	2.0
RZCMIN	f6bq21b1 Time to return of pulse (min)	80	2.1	1.7	0.0	7.0
RZCSEC	f6bq21b1 Time to return of pulse (sec)	80	23.4	18.1	0.0	58.0
RPULSE	f6bq21b2 Pulse returned	80	2.6	0.7	1.0	3.0
STPHR	f6bq22 Stroop/Rpt Nielsen stoptime (min)	174	14.4	3.0	9.0	22.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
STPMN	f6bq22 Stroop/Rpt Nielsen stoptime (sec)	175	27.5	17.6	0.0	58.0
STRPSENT	f6bq25(rev0) Stroop/RptNielsen disk sent	12	1.0	0.0	1.0	1.0
NIELDISK	f6bq23 Diskettes sent to CC	522	1.0	0.1	1.0	2.0
F6_DAYS	f06q2 Days from randomization	555	172.0	182.5	-11.0	533.0
NEWID	Patient ID	555	156.0	90.3	1.0	313.0
BTH_DAYS	f6bq4 Days rand. to water bath calibrati	552	57.5	216.9	-274.0	488.0
TMP_DAYS	f6bq5 Days rand. to finger probe calibra	552	25.2	1108.2	-25656.0	481.0

f6q3 Visit Nielsen Test performed

VIS_NUM	Frequency	Percent	Cumulative Frequency	Cumulative Percent
FV02	197	35.5	197	35.5
FV04	159	28.6	356	64.1
RV01	199	35.9	555	100.0

f6aq11a Prescription medication

MEDA	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	191	100.0	191	100.0

Frequency Missing = 364

f6aq11b Prescription medication

MEDB	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	87	100.0	87	100.0

Frequency Missing = 468

f6aq11c Prescription medication

MEDC	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	40	100.0	40	100.0

Frequency Missing = 515

Form 6A type

FMFYPA	Frequency	Percent	Cumulative Frequency	Cumulative Percent
NA01	235	42.5	235	42.5
NA02	187	33.8	422	76.3
NA03	131	23.7	553	100.0

Frequency Missing = 2

f6bq18a Specify other problem

OTHRMCK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	186	100.0	186	100.0

Frequency Missing = 369

f6b Form 6B type

FMYPB	Frequency	Percent	Cumulative Frequency	Cumulative Percent
<i>ff</i>				
NB01	235	42.6	235	42.6
NB02	187	33.9	422	76.4
NB03	130	23.6	552	100.0

Frequency Missing = 3