G.09.11.
RESTORATIVE SLEEP QUESTIONNAIRE (RSQ) IPM
[Option 1]

1.   Purpose

The Restorative Sleep Questionnaire (RSQ) is a measure assessing how an individual feels shortly after getting out of bed to start the day. This questionnaire is not a validated or published instrument. The questionnaire is a patient-reported instrument consisting of 11 items, 9 of which assess domains thought to be relevant to a sense of morning refreshment. A total score will be calculated as the rescaled average of the questionnaire items.

Permission to use the RSQ must be obtained from the University of California-Los Angeles (UCLA). Pfizer has received permission from UCLA for unlimited use of the RSQ company-wide. The RSQ is available for use free of charge. Questions regarding the instrument can be addressed to the Outcomes Research (OR) representative of the compound under study. The OR representative will serve as a central contact and manager of operational interactions with the instrument developer, Ron D. Hays. Dr. Hays' address is:

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[A date IPM (eg, A.3.6) should be used with this IPM.]

[A Language of Questionnaire IPM (eg, J.03.04 or J.03.05) must be used with this IPM.]

2.   Protocol

2.1   Guidelines

The protocol must define the time points at which this data will be collected. The protocol must specify whether patients will be completing this questionnaire at home or in the sleep laboratory.

2.2 Suggested Wording

The RSQ will be completed [insert "at home" or "in the sleep lab"] on Days *[insert desired time points or reference the Timetable of Visits and Procedures.]* A total score will be calculated as the rescaled average of the questionnaire items. The total score may range from 0 – 100; a higher total score indicating the subject feels more rested.

3. CRF Design

Restorative Sleep Questionnaire

☐ 3 Not Done

Please complete this questionnaire about half an hour after you get up in the morning and start the day. Try to complete the survey with as little distraction as possible. We want to know how you feel every day even if how you feel each day is the same.

For each question, please ✓ the box that best indicates how you feel (✓ only one box per question).

1. What time did you get up from sleep and start the day?

    └──┴──┘ └──┴──┘
      Hour   Minutes

2. What time is it right now?

    └──┴──┘ └──┴──┘
      Hour   Minutes

To what extent do you feel...

	Not at all	A little bit	Some	Very much	Completely
3. tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. sleepy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. in a good mood?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. rested?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. refreshed or restored?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. ready to start the day?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. energetic?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. mentally alert?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. grouchy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. Database Design

4.1 Annotated CRFs

Restorative Sleep Questionnaire

☐ 3 Not Done *NOTDONE*

Please complete this questionnaire about half an hour after you get up in the morning and start the day. Try to complete the survey with as little distraction as possible. We want to know how you feel every day even if how you feel each day is the same.

For each question, please ✓ the box that best indicates how you feel (✓ only one box per question).

1. What time did you get up from sleep and start the day?

L__I__J : L__I__J *RSQ01TM*
Hour   Minutes

2. What time is it right now?

L__I__J : L__I__J *RSQ02TM*
Hour   Minutes

To what extent do you feel...

		Not at all	A little bit	Some	Very much	Completely
3. tired?	*RSQ03*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. sleepy?	*RSQ04*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. in a good mood?	*RSQ05*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. rested?	*RSQ06*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. refreshed or restored?	*RSQ07*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. ready to start the day?	*RSO08*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. energetic?	*RSQ09*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. mentally alert?	*RSQ10*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. grouchy?	*RSQ11*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4.2   Extract View Description

There will be one record per patient per date/time.

FIELD NAME	FIELD DESCRIPTION	TYPE	DATA COLLECTION LENGTH	COMMENTS
NOTDONE	Not Done	C	8	Auxiliary Field
RSQ01TM	Time of Awakening	N	5	Key Field
RSQ02TM	Current Time	N	5	Key Field
RSQ03	Tired	N	1	Key Field
RSQ04	Sleepy	N	1	Key Field
RSQ05	Good Mood	N	1	Key Field
RSQ06	Rested	N	1	Key Field
RSQ07	Refreshed	N	1	Key Field
RSQ08	Ready to Start	N	1	Key Field
RSQ09	Energetic	N	1	Key Field
RSQ10	Alert	N	1	Key Field
RSQ11	Grouchy	N	1	Key Field

4.3   Field Calculations

FIELD NAME	DESCRIPTION	CALCULATION FORMULA	UNIT	BLANK ELEMENTS	EXPECTED RANGE, ROUNDING, SIGNIFICANT DIGITS
AVGSCR	RSQ Average Score	((6-RSQ03) + (6-RSQ04) + RSQ05 + RSQ06 + RSQ07 + RSQ08 + RSQ09 + RSQ10 + (6-RSQ11)) / 9	--	Blank if any component is missing	1 - 5
TOTSCR	RSQ Total Score	(AVGSCR –1)/ 25	--	Blank if AVGSCR is missing	0 - 100

[The study day from the referenced IPM should be associated with these data.]

5. Monitoring Guidelines

5.1 Source Document Verification

Not applicable as the CRF is the source document.

5.2 Internal Data Consistency Checks

As the CRF is a subject reported source document, it is impossible to retrieve missing information. Therefore, if the questionnaire is completed in a sleep lab, the site personnel must check that the questionnaire is appropriately completed before the subject leaves the sleep lab. If questionnaire is completed by a subject at home, it is not possible to retrieve missing data.

If two responses are checked for a single question, the most severe data will be entered into the database. For questions 3, 4 and 11, the most severe data is the larger numeric response. For questions 5-10, the most severe data is the smaller numeric response.

6. Data Verification

When it is determined that data from this IPM will be CRITICAL to a study, the following checks should be performed.

[Include the Data Verification checks specified in the referenced IPM.]

#	PARAMETERS	DESCRIPTION
1.	NOTDONE $^\wedge$ = '' and (RSQ01TM $^\wedge$= '' or RSQ02TM$^\wedge$= '' or RSQ03 $^\wedge$= '' or RSQ04 $^\wedge$= '' or RSQ05 $^\wedge$= '' or RSQ06 $^\wedge$= '' or RSQ07 $^\wedge$= '' or RSQ08 $^\wedge$= '' or RSQ09 $^\wedge$= '' or RSQ10 $^\wedge$= '' or RSQ11 $^\wedge$= '')	Not Done is indicated, but data are present on the CRF.
2.	NOTDONE = '' and (RSQ01TM = '' and RSQ02TM = '' and RSQ03 = '' and RSQ04 = '' and RSQ05 = '' and RSQ06 = '' and RSQ07 = ''and RSQ08 = '' and RSQ09 = '' and RSQ10 = '' and RSQ11 = '')	Not Done is blank and no data are present on the CRF.
3.	RSQ01TM = ''	Time of Awakening is blank.
4.	RSQ02TM = ''	Current Time is blank.
5.	RSQ03 = ''	Tired is blank.
6.	RSQ04 = ''	Sleepy is blank.
7.	RSQ05 = ''	Good Mood is blank.

#	PARAMETERS	DESCRIPTION
8.	RSQ06 = ''	Rested is blank.
9.	RSQ07 = ''	Refreshed is blank.
10.	RSQ08 = ''	Ready to Start is blank.
11.	RSQ09 = ''	Energetic is blank.
12.	RSQ10 = ''	Alert is blank.
13.	RSQ11 = ''	Grouchy is blank.
14.	RSQ01TM incomplete	Time of Awakening is incomplete.
15.	RSQ01TM invalid	Time of Awakening is invalid (e.g. 11:75).
16.	RSQ02TM incomplete	Current Time is incomplete.
17.	RSQ02TM invalid	Current Time is invalid (e.g. 11:75).
18.	RSQ02TM < RSQ01TM	Current Time is before Time of Awakening
19.	RSQ03: 1, 5	Tired is out of the range 1-5.
20.	RSQ04: 1, 5	Sleepy is out of the range 1-5.
21.	RSQ05: 1, 5	Good Mood is out of the range 1-5.
22.	RSQ06: 1, 5	Rested is out of the range 1-5.
23.	RSQ07: 1, 5	Refreshed is out of the range 1-5.
24.	RSQ08: 1, 5	Ready to start question is out of the range 1-5.
25.	RSQ09: 1, 5	Energetic is out of the range 1-5.
26.	RSQ10: 1, 5	Alert is out of the range 1-5.
27.	RSQ11: 1, 5	Grouchy is out of the range 1-5.

7. Individual Patient Data Display Requirements

7.1 CRF Tabulation Requirements

Appendix #
Patient Data Tabulation

Study Title Line 1
Study Title Line 2

Protocol:	Age (yr):	[Optional 1]:
Patient ID:	Race:	[Optional 2]:
Treatment Group:	Sex:	[Optional 3]:

Restorative Sleep Questionnaire

Study Day	Time of Awakening *RSQ01TM*	Current Time *RSQ02TM*	Tired *RSQ03*	Sleepy *RSQ04*	Good Mood *RSQ05*	Rested *RSQ06*	Refreshed *RSQ07*	Ready to Start *RSQ08*	Energetic *RSQ09*	Alert *RSQ10*	Grouchy *RSQ11*	Total Score *TOTSCR*
1	8:35	9:05	2	2	4	4	5	4	4	5	1	83.3

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7.2   Listing Table Requirements

Appendix #
Restorative Sleep Questionnaire
Title of Study (Line 1)
Title of Study (Line 2)
[optional: third title]

Protocol xxxx-xxx-xxx *[optional: subset information]*

Treatment Group	Patient ID	Study Day	Time of Awakening	Current Time	Total Score
Study Med 1	*1*		*RSQ01TM*	*RSQ02TM*	*TOTSCR*
		1	8:35	9:05	83.3
		2	8:25	8:55	87.3
...					
Study Med 2	*2*		*RSQ01TM*	*RSQ02TM*	*TOTSCR*
		1	8:20	8:55	65.6
		2	9:00	9:20	70.6
…					

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8. Summary Data Display Requirements

8.1 Summary Table Requirements

Appendix #
Summary of Restorative Sleep Questionnaire – Total Score

[Study Title]

Protocol xxxx-xxx-xxx

Total Score	Rxgrp 1 (N=xx)[a]	Rxgrp 2 (N=xx)	Rxgrp 3 (N=xx)
Time (Baseline)			
N[b]	23	23	23
Mean, SD	69.5, 4.55	69.5, 4.55	69.5, 4.55
Median	65.3	65.3	65.3
(Min, Max)	(33.4, 96.7)	(33.4, 96.7)	(33.4, 96.7)
Time (Timepoint X)			
N[b]	23	23	23
Mean, SD	69.5, 4.55	69.5, 4.55	69.5, 4.55
Median	65.3	65.3	65.3
(Min, Max)	(33.4, 96.7)	(33.4, 96.7)	(33.4, 96.7)
Time (Change from Baseline to Timepoint X)			
N[c]	23	23	23
Mean, SD	69.5, 4.55	69.5, 4.55	69.5, 4.55
Median	65.3	65.3	65.3
(Min, Max)	(33.4, 96.7)	(33.4, 96.7)	(33.4, 96.7)

[a] [This is the total number of patients in that treatment group]
[b] [This is the total number of subjects in that treatment group that answered the questionnaire]
[c] [This is the total number of subjects with data at both time points]

8.2 Summary Graphical Display Requirements

Not Applicable

9. Statistical Information

The relationship between Total Score (or the change from baseline, or the percent change from baseline) and the doses or the pharmacokinetic parameters (plasma concentrations, AUC's or Cmax's) may be analyzed with a linear model. Additional predictor variables such as subject effects or time post dose, or covariates such as age or gender, may be included in the linear model as deemed appropriate. For each effect, point estimates, standard errors, 95% confidence intervals and p-values for H_0: effect $= 0$ should be reported. For comparisons of interest among the effects, the same statistics should be reported.

IPM Appendices	
Appendix 1	
Appendix 2	
Appendix 3	
Appendix 4	
Appendix 5	
Appendix 6	Comment Document