Study #021 DFstudy30 Plate #030 DFplate30 Seq #003 DFseq30

Participant ID # n n — n n n n — n n
id_030

Today's Date d d (day) m m (month) y y (year)
v_date030

Baseline Questionnaire
Page 1 of 11

Demographics

bq1 1. Age: . . . . [n n] years

bq2 2. Gender: . . . . [1] Female [2] Male

bq3 3. What is your highest level of schooling or education?

- [1] Primary or grammar school
- [2] Some high school
- [3] Graduated from high school
- [4] Some college or university education
- [5] Graduated from college or university
- [6] None

bq4 4. Which of the following best describes your current employment status?

- [1] Working full-time
- [2] Working part-time
- [3] Homemaker full-time
- [4] Retired
- [5] Student
- [6] Temporarily not working
- [7] Unable to work because of health reasons and/or disabled

Ethnic Background

5. What is your ethnicity? ***Mark all that apply.***

- bq5_ca ☐ Caucasian
- bq5_hi ☐ Hispanic/Latino
- bq5_na ☐ Native American
- bq5_as ☐ Asian or Pacific Islander
- bq5_af ☐ African-American, Afro-Caribbean or other African Heritage

1 . 0 4
lang030 ver030

Study #021 DFstudy31 | Plate #031 DFplate31 | Seq #003 DFseq31

Participant ID # [n][n] — [n][n][n][n] — [n][n] id_031

Today's Date [d][d] day [m][m] month [y][y] year v_date031

Baseline Questionnaire

6. Please mark the ethnic origins of all of your biological grandparents (father's father, father's mother, mother's father, and mother's mother). ***Mark all that apply.***

bq6_n_eu ☐ Northern European
bq6_c_eu ☐ Central European
bq6_s_eu ☐ Southern European
bq6_e_eu ☐ Eastern European
bq6_m_ea ☐ Middle Eastern
bq6_e_me ☐ East Mediterranean
bq6_n_af ☐ North African
bq6_s_af ☐ Subsaharan African
bq6_n_am ☐ North American
bq6_n_in ☐ North American Indian
bq6_me ☐ Mexican
bq6_c_am ☐ Central American
bq6_ca ☐ Caribbean
bq6_s_am ☐ South American
bq6_l_in ☐ Latin American Indian
bq6_ch_h ☐ Chinese (Han)
bq6_ch_n ☐ Chinese (Non-Han)
bq6_ja ☐ Japanese
bq6_ko ☐ Korean
bq6_fi ☐ Filipino
bq6_s_as ☐ South-East Asian
bq6_in ☐ Indian sub-continent
bq6_oth ☐ Other

Tobacco Use History

bq7 7. Do you currently smoke cigarettes? . . . . *yes* [1] *no* [2] → ***Go to item10***

bq8 8. Have you ever smoked cigarettes? . . . . *yes* [1] *no* [2] → ***Go to item 12***

bq9 9. At what age did you stop smoking? . . . . [n][n] years

bq10 10. At what age did you start smoking? . . . . [n][n] years

bq11_num 11. Approximately how many cigarettes a day do/did you smoke? . . . . [n][n] cigarettes per day bq11_ck ☐ Less than 1 cigarette per day

bq12 12. Do you use any other forms of tobacco? . . . . *yes* [1] *no* [2] → ***Go to item 13***

12a. Which of the following forms of tobacco do you use? ***Mark all that apply.***

bq12a_ci ☐ Cigars bq12a_pi ☐ Pipe bq12a_sm ☐ Smokeless or chewing tobacco

Study #021 Plate #032 Seq #003

DFstudy32 DFplate32 DFseq32

Participant ID # n n — n n n n — n n

id_032

Today's Date d d m m y y

day month year

v_date032

Baseline Questionnaire

bq13 13. Do you use any other forms of nicotine? . . . . *yes* 1 *no* 2 → ***Go to item 14***

13a. Which of the following forms of nicotine do you use? ***Mark all that apply.***

bq13a_p ☐ Patch bq13a_c ☐ Chewing gum bq13a_o ☐ Other

General Physical and Emotional Health

These next questions are about your health now and your current daily activities.
Please try to answer each question as accurately as you can.

bq14 *14. In general, would you say your health is:

1 Excellent 2 Very Good 3 Good 4 Fair 5 Poor

*The following questions are about activities you might do during a typical day.
Does your health now limit you in these activities? If so, how much?

		Yes, limited a lot	*Yes, limited a little*	*No, not limited at all*
bq15	*15. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
bq16	*16. Climbing several flights of stairs	1	2	3

*During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		All of the time	*Most of the time*	*Some of the time*	*A little of the time*	*None of the time*
bq17	*17. Accomplished less than you would like	1	2	3	4	5
bq18	*18. Were limited in the kind of work or other activities	1	2	3	4	5

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Study #021 Plate #033 Seq #003

DFstudy33 DFplate33 DFseq33

Participant ID # n n — n n n n — n n

id_033

Today's Date d d | m m | y y

day month year

v_date033

Baseline Questionnaire

*During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		All of the time	*Most of the time*	*Some of the time*	*A little of the time*	*None of the time*
bq19	*19. Accomplished less than you would like	1	2	3	4	5
bq20	*20. Did work or other activities less carefully than usual	1	2	3	4	5

bq21 *21. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- 1 Not at all
- 2 A little bit
- 3 Moderately
- 4 Quite a bit
- 5 Extremely

*These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

		All of the time	*Most of the time*	*Some of the time*	*A little of the time*	*None of the time*
bq22	*22. Have you felt calm and peaceful?	1	2	3	4	5
bq23	*23. Did you have a lot of energy?	1	2	3	4	5
bq24	*24. Have you felt downhearted and depressed?	1	2	3	4	5

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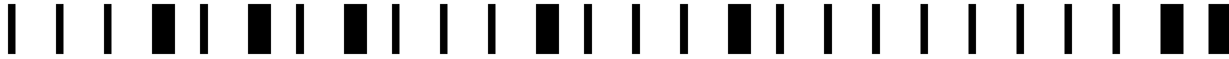
lang033 ver033



Study #021 DFstudy34   Plate #034 DFplate34   Seq #003 DFseq34

Participant ID # n n — n n n n — n n (id_034)   **Today's Date** d d (day) m m (month) y y (year) v_date034

Baseline Questionnaire

bq25 25. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- 1 All of the time
- 2 Most of the time
- 3 Some of the time
- 4 A little bit of the time
- 5 None of the time

Over the last 2 WEEKS how often have you felt bothered by the following problems:

bq26 26. Little interest or pleasure doing things

- 1 Not at all
- 2 Several days
- 3 More than half the days
- 4 Nearly every day

bq27 27. Feeling down, depressed or hopeless

- 1 Not at all
- 2 Several days
- 3 More than half the days
- 4 Nearly every day

bq28 28. Trouble falling or staying asleep, or sleeping too much

- 1 Not at all
- 2 Several days
- 3 More than half the days
- 4 Nearly every day

bq29 29. Feeling tired or having little energy

- 1 Not at all
- 2 Several days
- 3 More than half the days
- 4 Nearly every day

bq30 30. Poor appetite or overeating

- 1 Not at all
- 2 Several days
- 3 More than half the days
- 4 Nearly every day

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1 . 0 4 (lang034 ver034)

Study #021 DFstudy35 Plate #035 DFplate35 Seq #003 DFseq35

Participant ID # n n — n n n n — n n id_035

Today's Date d d (day) m m (month) y y (year) v_date035

Baseline Questionnaire

bq31 31. Feeling bad about yourself, or that you are a failure or have let yourself or your family down

- [1] Not at all
- [2] Several days
- [3] More than half the days
- [4] Nearly every day

bq32 32. Trouble concentrating on things, such as reading the newspaper or watching television

- [1] Not at all
- [2] Several days
- [3] More than half the days
- [4] Nearly every day

bq33 33. Moving or speaking so slow that other people could have noticed.
Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual

- [1] Not at all
- [2] Several days
- [3] More than half the days
- [4] Nearly every day

bq34 34. Thoughts that you would be better off dead, or of hurting yourself in some way

- [1] Not at all
- [2] Several days
- [3] More than half the days
- [4] Nearly every day

Reproductive and Hormonal History

To be completed by women only. Men go to item 44.

bq35 35. How old were you when you first began having you menstrual period? . . . . . n n years

bq36 36. Have you started or experienced menopause? . . . . . *yes* [1] *no* [2] → ***Go to item 38***

bq37 37. How old were you at the start of menopause?. . . . . n n years

bq38 38. Have you had significant vaginal dryness? . . . . . *yes* [1] *no* [2]

bq39 39. How many times have you been pregnant in your lifetime? . . . . . n n → ***If 0, go to item 42***
Please include live births, still births, terminations/abortions, miscarriages and tubal pregnancies.

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lang035 ver035

Study #021 DFstudy36 Plate #036 DFplate36 Seq #003 DFseq36

Participant ID # n n — n n n n — n n id_036

Today's Date d d (day) m m (month) y y (year) v_date036

Baseline Questionnaire

40. How many of these pregnancies resulted in:

bq40a 40a. Full-term delivery? . . . . n n

bq40b 40b. Premature delivery (more than 3 weeks before due date)? . . . . n n

bq40c 40c. Miscarriage during the 1st trimester? . . . . n n

bq40d 40d. Miscarriage during the 2nd trimester? . . . . n n

bq40e 40e. Stillbirth during the 3rd trimester? . . . . n n

bq41 41. Have you ever had a child born with complete congenital heart block? . . . . *yes* 1 *no* 2

bq42 42. Do you currently take female hormones (birth control pills, estrogen and/or progestins as pills, patches or injections, etc.)? . . . . *yes* 1 *no* 2

bq43 43. Have you had a hysterectomy? . . . . *yes* 1 *no* 2

Symptoms Affecting Your Mouth

bq44 44. Does your mouth feel dry? . . . . *yes* 1 *no* 2 → ***Go to item 45***

44a. When does your mouth feel dry? ***Mark all that apply.***

- ☐ In the morning bq44 a_mo
- ☐ In the afternoon bq44 a_af
- ☐ At night bq44 a_ni

bq44b 44b. When did your mouth first start feeling dry? . . . . n n (month) n n (year)

bq45 45. Does your mouth feel dry when eating a meal? . . . . *yes* 1 *no* 2

bq46 46. Do you have difficulty swallowing any foods? . . . . *yes* 1 *no* 2

bq47 47. Do you need to sip liquids to swallow dry foods? . . . . *yes* 1 *no* 2

1 . 0 4 lang036 ver036

Study #021 DFstudy37 Plate #037 DFplate37 Seq #003 DFseq37

Participant ID # n n — n n n n — n n
id_037

Today's Date d d (day) m m (month) y y (year)
v_date037

Baseline Questionnaire

bq48 48. Is the amount of saliva in your mouth:

1 Too little   2 Too much   3 You don't notice it

bq49 49. How often do you use artificial saliva?

1 10 times a day or more   3 1 to 3 times a day
2 4 to 9 times a day   4 Never

bq50 50. Can you eat a cracker without drinking a fluid/liquid? . . . . *yes* 1 *no* 2

bq51 51. Do you have a burning sensation on your tongue or in other parts of your mouth? . . *yes* 1 *no* 2 → ***Go to item 52***

51a. In which parts of your mouth do you have a burning sensation? ***Mark all that apply.***

bq51a_to ☐ Tongue   bq51a_ch ☐ Cheeks
bq51a_pa ☐ Palate (roof of mouth)   bq51a_gu ☐ Gums
bq51a_li ☐ Lips   bq51a_en ☐ Entire mouth

bq52 52. How would you describe your dental and oral heath in general?

1 Excellent   2 Good   3 Fair   4 Poor

bq53 53. In general, how often do you brush your teeth?

1 Never   2 Occasionally   3 Once per day   4 Twice per day   5 Three times per day or more

bq54 54. In general, how often do you floss your teeth?

1 Never   2 Occasionally   3 Once per day   4 More than once a day

bq55 55. How often do you clean between your teeth with a toothpick?

1 Never   2 Occasionally   3 Once per day   4 More than once a day

bq56 56. In the past year, have you avoided eating certain foods you wanted because they made your mouth hurt? . . . . . *yes* 1 *no* 2

1 . 0 4
lang037 ver037

Study #021 DFstudy38 | Plate #038 DFplate38 | Seq #003 DFseq38

Participant ID # n n — n n n n — n n id_038

Today's Date d d (day) m m (month) y y (year) v_date038

Baseline Questionnaire

bq57 57. Have you experienced any change/loss in your sense of taste? . . . . *yes* 1 *no* 2

bq58 58. Do you have a regular source of dental care - that is, a dentist or dental clinic that you visit on a regular basis to get your teeth examined, cleaned, or cared for? *yes* 1 *no* 2

bq59 59. About how long has it been since you were last treated or examined by a dentist or a hygienist?

1 Less than 3 months
2 3 to 6 months
3 6 to 12 months
4 1-2 years
5 2-3 years
6 3-5 years
7 More than 5 years
8 Never

bq60 60. Approximately how many times have you visited the dentist in the past year?

1 0 2 1 3 2 4 3 5 4 6 5 7 6 or more

61. During the past 12 months have you had any of the following dental procedures?
Mark all that apply.

- bq61_or ☐ Oral examination
- bq61_ra ☐ Radiographs or x-rays of the teeth
- bq61_te ☐ Teeth cleaned by a dentist or hygienist
- bq61_t_f ☐ A tooth filled or crown made
- bq61_ort ☐ Orthodontic treatment or braces
- ☐ Any gum treatment or gum surgery bq61_gu
- ☐ A tooth or teeth removed bq61_t_r
- ☐ A biopsy taken from your mouth or lip bq61_bi
- ☐ None bq61_no

Symptoms Affecting Your Eyes

bq62 62. Do your eyes feel dry? . . . . *yes* 1 *no* 2 → ***Go to item 63***

62a. When do your eyes feel dry? ***Mark all that apply.***

☐ In the morning bq62a_mo ☐ In the afternoon bq62a_af ☐ At night bq62a_ni

bq62b 62b. When did your eyes first start feeling dry? . . . . n n (month) n n (year)

1 . 0 4
lang038 ver038

Study #021 DFstudy39 Plate #039 DFplate39 Seq #003 DFseq39

Participant ID # n n — n n n n — n n id_039

Today's Date d d (day) m m (month) y y (year) v_date039

Baseline Questionnaire

	None of the time	Some of the time	Half of the time	Most of the time	All of the time
bq63 63. How often do you have redness in your eyes?	1	2	3	4	5
bq64 64. How often do your eyes itch?	1	2	3	4	5
bq65 65. How often do you have excessive tears?	1	2	3	4	5

	yes	no
bq66 66. Are you able to produce tears?	1	2

bq67 67. How often do you use artificial tears?

1 10 times a day or more
2 4 to 9 times a day
3 1 to 3 times a day
4 Never → ***Go to item 68***

bq67a 1 2 3 4

67a. What type of artificial tears do you use? ***Mark all that apply.***

☐ Bottles (with preservatives) bq67a_bo
☐ Single vials (without preservatives) bq67a_si
☐ Ointment bq67a_oi
☐ Don't know bq67a_dk

	yes	no
bq67b 67b. Does your vision improve with artificial tears?	1	2
bq68 68. Do you use any other type of medicated drops in your eyes?	1	2 → ***Go to item 69***

68a. What type of medicated drops do you use? ***Mark all that apply.***

☐ Whitening/ vasoconstrictor bq68a_wh
☐ Cyclosporine/ restasis bq68a_cy
☐ Traditional bq68a_tr
☐ Antibiotic bq68a_an
☐ Steroid bq68a_st
☐ Other bq68a_ot

bq68a 1 3 5 2 4 6

69. During the LAST WEEK have you experienced any of the following symptoms with your eyes:

	None of the time	Some of the time	Half of the time	Most of the time	All of the time
bq69a 69a. Light sensitivity	1	2	3	4	5
bq69b 69b. Gritty or scratchy sensation	1	2	3	4	5
bq69c 69c. Burning or stinging	1	2	3	4	5

1 . 0 4
lang039 ver039

Study #021 DFstudy40 Plate #040 DFplate40 Seq #003 DFseq40

Participant ID # n n – n n n n – n n id_040 **Today's Date** d d / m m / y y (day month year) v_date040

Baseline Questionnaire

		None of the time	*Some of the time*	*Half of the time*	*Most of the time*	*All of the time*
bq69d	69d. Blurred vision.	1	2	3	4	5
bq69e	69e. Vision that fluctuates with blinking.	1	2	3	4	5
bq69f	69f. Tearing	1	2	3	4	5
bq69g	69g. Pain or burning in the middle of the night or upon waking in the morning	1	2	3	4	5

	70. Have you experienced eye irritation while performing any of these activities during the last week:	*None of the time*	*Some of the time*	*Half of the time*	*Most of the time*	*All of the time*	*Not applicable*
bq70a	70a. Reading or driving a car for a long period	1	2	3	4	5	6
bq70b	70b. Watching TV or working on a computer for an extended period	1	2	3	4	5	6

	71. Have your eyes felt uncomfortable in any of the following situations during the last week	*None of the time*	*Some of the time*	*Half of the time*	*Most of the time*	*All of the time*
bq71a	71a. Wind or air drafts	1	2	3	4	5
bq71b	71b. Places with low humidity such as air conditioned or heated buildings or airplanes	1	2	3	4	5

bq72 72. Have any of your immediate blood related family members (see below) been diagnosed with Sjögren's Syndrome? *yes* 1 *no* 2 *not sure* 3

(no / not sure) → ***Go to Baseline Medical History Questionnaire***

72a. Which family member(s)? ***Mark all that apply.***

bq72a_mo ☐ Mother	bq72a_so ☐ Son	☐ Aunt bq72a_au	bq72a_ni ☐ Niece
bq72a_fa ☐ Father	bq72a_da ☐ Daughter	☐ Uncle bq72a_un	☐ Other bq72a_ot
bq72a_si ☐ Sister	bq72a_gm ☐ Grandmother	☐ Cousin bq72a_co	
bq72a_br ☐ Brother	bq72a_gf ☐ Grandfather	☐ Nephew bq72a_ne	

CLINIC USE ONLY

bq73 73. Was this questionnaire administered by study staff? *yes* 1 *no* 2

Staff Initials ☐☐☐ staff_init040

Staff Signature and Date ______________________

1 . 0 4 lang040 ver040