Follow-up Questionnaire
Page 1 of 10

Demographics

1. What is your highest level of schooling or education? 
   - [ ] Primary or grammar school
   - [ ] Some high school
   - [ ] Graduated from high school
   - [ ] Some college or university education
   - [ ] Graduated from college or university
   - [ ] None

2. Which of the following best describes your current employment status?
   - [ ] Working full-time
   - [ ] Working part-time
   - [ ] Homemaker full-time
   - [ ] Retired
   - [ ] Student
   - [ ] Temporarily not working
   - [ ] Unable to work because of health reasons and/or disabled

Tobacco Use History

3. Do you currently smoke cigarettes? ........................................... [ ] yes [ ] no
   Go to item 5

4. Approximately how many cigarettes a day do you smoke? ............. [ ] cigarettes per day
   Less than 1 cigarette per day

5. Do you use any other forms of tobacco? .................................... [ ] yes [ ] no
   Go to item 6

   5a. Which of the following forms of tobacco do you use? **Mark all that apply.**
   - [ ] Cigars
   - [ ] Pipe
   - [ ] Smokeless or chewing tobacco

6. Do you use any other forms of nicotine? ................................. [ ] yes [ ] no
   Go to item 7

   6a. Which of the following forms of nicotine do you use? **Mark all that apply.**
   - [ ] Patch
   - [ ] Chewing gum
   - [ ] 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.

7. In general, would you say your health is:


   * 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?

8. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

   Yes, limited a lot  1
   Yes, limited a little  2
   No, not limited at all  3

9. Climbing several flights of stairs

   Yes, limited a lot  1
   Yes, limited a little  2
   No, not limited at all  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?

10. Accomplished less than you would like

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

11. Were limited in the kind of work or other activities

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

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**Follow-up Questionnaire**  
*Study #021*  
*Follow-up Questionnaire (FQ3)*  
*Plate #332*  
*Seq #005*

---

### *12. Accomplished less than you would like*  
<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### *13. Did work or other activities less carefully than usual*  
<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### *14. During the past 4 weeks, how much pain interfered with your normal work (including both work outside the home and housework)?*  
- Not at all
- A little bit
- Moderately
- Quite a bit
- 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...*

### *15. Have you felt calm and peaceful?*  
<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### *16. Did you have a lot of energy?*  
<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### *17. Have you felt downhearted and depressed?*  
<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

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(SF12v2 Standard, US Version 2.0)  
SICCA FQ v1.01 - Jan 16, 2007*
*18. 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:

**19. Little interest or pleasure doing things**

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

**20. Feeling down, depressed or hopeless**

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

**21. 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

**22. Feeling tired or having little energy**

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

**23. 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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Follow-up Questionnaire
Page 5 of 10

fq24 24. Feeling bad about yourself, or that you are a failure or have let yourself or your family down

[ ] Not at all  [ ] More than half the days
[ ] Several days  [ ] Nearly every day

fq25 25. Trouble concentrating on things, such as reading the newspaper or watching television

[ ] Not at all  [ ] More than half the days
[ ] Several days  [ ] Nearly every day

fq26 26. 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

[ ] Not at all  [ ] More than half the days
[ ] Several days  [ ] Nearly every day

fq27 27. Thoughts that you would be better off dead, or of hurting yourself in some way

[ ] Not at all  [ ] More than half the days
[ ] Several days  [ ] Nearly every day

Reproductive and Hormonal History
To be completed by women only. Men go to item 35.

fq28 28. Since your last study visit, how many times have you been pregnant? Please include live births, still births, terminations/abortions, miscarriages and tubal pregnancies.

[ ]

If 0, go to item 31

29. How many of these pregnancies resulted in:

fq29a 29a. Full-term delivery?  

[ ]

fq29b 29b. Premature delivery (more than 3 weeks before due date)?

[ ]

fq29c 29c. Miscarriage during the 1st trimester?

[ ]

fq29d 29d. Miscarriage during the 2nd trimester?

[ ]

fq29e 29e. Stillbirth during the 3rd trimester?

[ ]
Follow-up Questionnaire
Page 6 of 10

30. Since your last study visit, have you had a child born with complete congenital heart block?
   yes  no
31. Have you started or experienced menopause?
   yes  no  Go to item 32
31a. How old were you at the start of menopause?
   years
32. Do you currently take female hormones (birth control pills, estrogen and/or progestins as pills, patches or injections, etc.)?
   yes  no
33. Since your last SICCA study visit, have you had a hysterectomy?
   yes  no
34. Since your last SICCA study visit, have you had significant vaginal dryness?
   yes  no

Symptoms Affecting Your Mouth

35. Does your mouth feel dry?
   yes  no  Go to item 36
35a. When does your mouth feel dry? Mark all that apply.
   - In the morning
   - In the afternoon
   - At night
35b. Compared with your first SICCA visit (approximately 2 years ago), does your mouth feel?
   - the same
   - drier
   - like you have more saliva
36. Does your mouth feel dry when eating a meal?
   yes  no
37. Do you have difficulty swallowing any foods?
   yes  no
38. Do you need to sip liquids to swallow dry foods?
   yes  no
39. Is the amount of saliva in your mouth:
   1 Too little  2 Too much  3 You don’t notice it

40. 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

41. Can you eat a cracker without drinking a fluid/liquid? ............................
   yes  no

42. Do you have a burning sensation on your tongue or in other parts of your mouth?
   yes  no

42a. In which parts of your mouth do you have a burning sensation? *Mark all that apply.*
   Tongue  Cheeks  Palate (roof of mouth)  Gums  Lips  Entire mouth

43. How would you describe your dental and oral health in general?
   1 Excellent  2 Good  3 Fair  4 Poor

44. 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

45. In general, how often do you floss your teeth?
   1 Never  2 Occasionally  3 Once per day  4 More than once a day

46. 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

47. In the past year, have you avoided eating certain foods you wanted because they made your mouth hurt?
   yes  no

SICCA FQ v1.01 - Jan 16, 2007
Follow-up Questionnaire
Page 8 of 10

**53.** Do your eyes feel dry? ..........................  

53a. When do your eyes feel dry? Mark all that apply.

- In the morning [ ]  
- In the afternoon [ ]  
- At night [ ]

53b. Compared with your first SICCA visit (approximately 2 years ago), do your eyes feel:

- the same [ ]  
- drier [ ]
- more moist [ ]

**54.** Have you experienced any change/loss in your sense of taste? .............  

**55.** 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?  

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

- Less than 3 months [ ]  
- 3 to 6 months [ ]  
- 6 to 12 months [ ]  
- 1-2 years [ ]  
- 2-3 years [ ]  
- 3-5 years [ ]  
- More than 5 years [ ]  
- Never [ ]

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

- Oral examination [ ]  
- Radiographs or x-rays of the teeth [ ]  
- Teeth cleaned by a dentist or hygienist [ ]  
- Orthodontic treatment or braces [ ]  
- Any gum treatment or gum surgery [ ]  
- A tooth or teeth removed [ ]  
- A biopsy taken from your mouth or lip [ ]  
- A tooth filled or crown made [ ]  
- None [ ]

**58.** Have you experienced any change/loss in your sense of taste?  

**59.** 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?  

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

- Less than 3 months [ ]  
- 3 to 6 months [ ]  
- 6 to 12 months [ ]  
- 1-2 years [ ]  
- 2-3 years [ ]  
- 3-5 years [ ]  
- More than 5 years [ ]  
- Never [ ]

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

- Oral examination [ ]  
- Radiographs or x-rays of the teeth [ ]  
- Teeth cleaned by a dentist or hygienist [ ]  
- Orthodontic treatment or braces [ ]  
- Any gum treatment or gum surgery [ ]  
- A tooth or teeth removed [ ]  
- A biopsy taken from your mouth or lip [ ]  
- A tooth filled or crown made [ ]  
- None [ ]
Follow-up Questionnaire (FQ9)

Page 9 of 10

54. How often do you have redness in your eyes?  

- None of the time
- Some of the time
- Half of the time
- Most of the time
- All of the time

55. How often do your eyes itch?  

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

56. How often do you have excessive tears?  

- None of the time
- Some of the time
- Half of the time
- Most of the time
- All of the time

57. Are you able to produce tears?  

- Yes
- No

58. How often do you use artificial tears?  

Mark all that apply.

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

58a. What type of artificial tears do you use?  

Mark all that apply.

- Bottles
- Single vials (without preservatives)
- Ointment
- Don't know

58b. Does your vision improve with artificial tears?  

- No
- Yes

59. Do you use any other type of medicated drops in your eyes?  

Mark all that apply.

- Whitening/vasoconstrictor
- Antibiotic
- Cyclosporine/restasis
- Traditional
- Steroid
- Other

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

60a. Light sensitivity  

- None of the time
- Some of the time
- Half of the time
- Most of the time
- All of the time

60b. Gritty or scratchy sensation  

- None of the time
- Some of the time
- Half of the time
- Most of the time
- All of the time

60c. Burning or stinging  

- None of the time
- Some of the time
- Half of the time
- Most of the time
- All of the time
### Follow-up Questionnaire

**Page 10 of 10**

<table>
<thead>
<tr>
<th>Question</th>
<th>None of the time</th>
<th>Some of the time</th>
<th>Half of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>60d. Blurred vision.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>60e. Vision that fluctuates with blinking.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>60f. Tearing</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>60g. Pain or burning in the middle of the night or upon waking in the morning</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

61. Have you experienced eye irritation while performing any of these activities during the last week:

<table>
<thead>
<tr>
<th>Question</th>
<th>None of the time</th>
<th>Some of the time</th>
<th>Half of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>61a. Reading or driving a car for a long period</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>61b. Watching TV or working on a computer for an extended period</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

62. Have your eyes felt uncomfortable in any of the following situations during the last week:

<table>
<thead>
<tr>
<th>Question</th>
<th>None of the time</th>
<th>Some of the time</th>
<th>Half of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>62a. Wind or air drafts</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>62b. Places with low humidity such as air conditioned or heated buildings or airplanes</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

63. Since your last study visit, have you found out that any of your immediate blood related family members (see below) have been diagnosed with Sjögren’s syndrome?

63a. Which family member(s)? Mark all that apply.

- [ ] Mother  
- [ ] Father  
- [ ] Sister  
- [ ] Brother  
- [ ] Son  
- [ ] Daughter  
- [ ] Grandmother  
- [ ] Grandfather  
- [ ] Aunt  
- [ ] Uncle  
- [ ] Cousin  
- [ ] Niece  
- [ ] Nephew  
- [ ] Other

**Go to Follow-up Medical History Questionnaire**

64. Was this questionnaire administered by study staff?  

- [ ] Yes  
- [ ] No  
- [ ] Not sure

---

**Staff Initials**  

**Staff Signature and Date**  

1.01