Participant Screening Questionnaire - Page 1 of 5

Read “Introduction”.

1. Are you 21 years of age or older? ......................................................
   yes 1 no 2 DEFER Go to item 17

2. Are you currently pregnant? .................................................................
   yes 1 no 2 not sure DEFER

3. I need to ask you about general health conditions you currently have or have had in the past. Please answer yes or no after each condition I read. Have you ever been diagnosed with:
   [Checkboxes for each condition]

   3a. Rheumatoid Arthritis by a rheumatologist .................................
       yes 1 no 2 not sure Go to item 3b

   3ai. SICCA Physician Confirmation of RA Diagnosis form received? yes 1 no 2 Cannot obtain Go to item 3b

   3bi. SICCA Physician Confirmation of SLE Diagnosis form received? yes 1 no 2 Cannot obtain PENDING

   3c. Systemic Sclerosis (Scleroderma) or CREST .............................
       yes 1 no 2 not sure INELIGIBLE

   3d. Undifferentiated or Mixed Connective Tissue Disease. .............
       yes 1 no 2 not sure INELIGIBLE

   3e. Polymyositis or Dermatomyositis ..............................................
       yes 1 no 2 not sure INELIGIBLE

   3f. HIV disease or AIDS .................................................................
       yes 1 no 2 not sure INELIGIBLE

   3g. Hepatitis C ...............................................................
       yes 1 no 2 not sure INELIGIBLE

   3h. Sarcoidosis. ..............................................................
       yes 1 no 2 not sure INELIGIBLE

   3i. Amyloidosis ............................................................
       yes 1 no 2 not sure INELIGIBLE

   3j. Graft versus Host Disease ....................................................
       yes 1 no 2 not sure INELIGIBLE

   (after bone marrow transplantation for cancer treatment)

4. Do you currently have active tuberculosis? .........................................
   yes 1 no 2 not sure DEFER

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5. Have you ever had radiation therapy to your head or neck for cancer treatment?

6. Were you referred to the Sjögren’s Syndrome Registry by a physician, dentist, or other clinician who suspects you have Sjögren’s syndrome?

7. Have you ever been diagnosed with Sjögren’s syndrome?

7a. At what age were you diagnosed?

8. Does your mouth feel dry?

9. Do you now have enlarged salivary glands (submandibular or parotid) or have they been enlarged in the past year?

9a. Are they enlarged on both sides of your face?

10. Have you recently had frequent dental decay or cavities?

11. Do your eyes feel dry?

12. Are you currently being treated with daily eye drops for glaucoma?

13. Have you had corneal surgery in the last 5 years to correct your vision?
14. Have you had cosmetic surgery on your eyelids in the last 5 years?  
- [ ] yes  
- [ ] no  
- [ ] not sure

15a. What type of contact lenses do you wear?  
- [ ] 1 Hard contacts  
- [ ] 2 Daily wear soft contacts  
- [ ] 3 Extended wear soft contacts

15b. What is the average number of hours per day that you wear contact lenses?  
- [ ] 1 1-6 hours per day  
- [ ] 2 Greater than 6 hours per day  
- [ ] 3 Not daily, only occasionally

15c. If you are eligible to participate in the registry as a potential pSS/sSS Case, are you willing to not wear your contact lenses for 7 days prior to your baseline eye exam?  
- [ ] yes  
- [ ] no

16. How did you hear about this study?  
- [ ] Sjögren's syndrome clinic  
- [ ] Dentist  
- [ ] Rheumatologist  
- [ ] Ophthalmologist (eye doctor)  
- [ ] Other doctor  
- [ ] Support group/seminar  
- [ ] Website/internet  
- [ ] Friend/relative  
- [ ] Advertisement (conference, journal, etc.)  
- [ ] Other
Participant ID # — —
Visit Date day month year

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Eligibility

17. Based upon screening, is the candidate eligible? 
   yes no Pending
   1 2 3
   Read “Pending statement” and go to Willingness to Participate

17a. Reason(s) for ineligibility/deferral. Mark all that apply.

  1 Candidate is < 21 years of age (NO to question 1)
  1 Candidate responded YES at least once to questions 2, 3c-5
  1 Candidate gave all NO or NOT SURE responses to questions 6-11
  1 Candidate responded YES at least once to questions 12-14 or NO to 15c
  1 Candidate unwilling to request Physician Confirmation of RA/SLE Diagnosis (CANNOT OBTAIN to question 3ai or 3bi)
  1 Unable to obtain Physician Confirmation of RA Diagnosis from MD (CANNOT OBTAIN to question 3ai)
  1 Unable to obtain Physician Confirmation of SLE Diagnosis from MD (CANNOT OBTAIN to question 3bi)

After completing item 17a:
If candidate is ineligible, read “Conclusion 1-Ineligible” and go to item 22.
If candidate is deferred, read “Conclusion 1-Deferred” and go to item 22.

Read “Willingness to Participate”.

17b. Does candidate agree to participate in the study? 
   yes no
   1 2
   Read “Conclusion 2” and go to item 22

Read Other Conditions

Has a doctor ever told you that you had any of the following conditions?

18. Thyroid disease 
   yes no not sure
   1 2 3
   If YES to ANY, complete Baseline Systemic Diagnoses Confirmation Form after contacting participant’s physician

19. Liver disease

20. Kidney disease

21. Lymphoma

22. How was this interview conducted? 
   telephone in person
   1 2
23. Is your ethnic background Hispanic, Latino or other Spanish descent? ........ yes no

24. What is your racial background? Please choose as many categories as apply to you.

- Caucasian/White/Middle Eastern
- African-American/Black/Haitian
- Asian
- American Indian/Native American/Alaskan Native
- Native Hawaiian/Pacific Islander
- Other

25. Date of final review of Participant Screening Questionnaire with participant: ....... dd mm yy