



Study #021

Plate #010

Seq #000

Participant ID # - -

Visit Date
 day month year

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Read "Introduction".

ps1 1. Are you 21 years of age or older? 1 2 3 → **DEFER**
 Go to item 17

ps2 2. Are you currently pregnant? 1 2 3 → **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:

ps3a 3a. Rheumatoid Arthritis by a rheumatologist 1 2 3 → **Go to item 3b**

ps3ai 3ai. SICCA Physician Confirmation of RA Diagnosis form received? 1 2 3 → **INELIGIBLE**
PENDING

ps3b 3b. Lupus (Systemic Lupus Erythematosus) 1 2 3 → **Go to item 3c**

ps3bi 3bi. SICCA Physician Confirmation of SLE Diagnosis form received? 1 2 3 → **INELIGIBLE**
PENDING

ps3c 3c. Systemic Sclerosis (Scleroderma) or CREST 1 2 3 → **INELIGIBLE**

ps3d 3d. Undifferentiated or Mixed Connective Tissue Disease. 1 2 3 → **INELIGIBLE**

ps3e 3e. Polymyositis or Dermatomyositis 1 2 3 → **INELIGIBLE**

ps3f 3f. HIV disease or AIDS 1 2 3 → **INELIGIBLE**

ps3g 3g. Hepatitis C 1 2 3 → **INELIGIBLE**

ps3h 3h. Sarcoidosis. 1 2 3 → **INELIGIBLE**

ps3i 3i. Amyloidosis 1 2 3 → **INELIGIBLE**

ps3j 3j. Graft versus Host Disease. (after bone marrow transplantation for cancer treatment) 1 2 3 → **INELIGIBLE**

ps4 4. Do you currently have active tuberculosis? 1 2 3 → **DEFER**



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Plate #014

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ps5_014 5. Have you ever had radiation therapy to your head or neck for cancer treatment?

yes no not sure
[1] [2] [3]

INELIGIBLE

ps6_014 6. Were you referred to the Sjögren's Syndrome Registry by a physician, dentist, or other clinician who suspects you have Sjögren's syndrome?

yes no not sure
[1] [2] [3]

ps7_014 7. Have you ever been diagnosed with Sjögren's syndrome?

[1] [2] [3]

Go to item 8

ps7a_014 7a. At what age were you diagnosed? [][] years

ps8_014 8. Does your mouth feel dry?

[1] [2] [3]

ps9_014 9. Do you now have enlarged salivary glands (submandibular or parotid) or have they been enlarged in the past year?

[1] [2] [3]

Go to item 10

ps9a_014 9a. Are they enlarged on both sides of your face?

[1] [2] [3]

ps10_014 10. Have you recently had frequent dental decay or cavities?

[1] [2] [3]

ps11_014 11. Do your eyes feel dry?

[1] [2] [3]

If ALL NO or NOT SURE, INELIGIBLE

ps12_014 12. Are you currently being treated with daily eye drops for glaucoma?

[1] [2] [3]

INELIGIBLE

ps13_014 13. Have you had corneal surgery in the last 5 years to correct your vision?

[1] [2] [3]

INELIGIBLE



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Plate #015

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ps14_015 14. Have you had cosmetic surgery on your eyelids in the last 5 years? ...
yes no not sure
[1] [2] [3] → INELIGIBLE

ps15_015 15. Do you currently wear contact lenses? [1] [2] → Go to item 16

ps15a 15a. What type of contact lenses do you wear?

- [1] Hard contacts [2] Daily wear soft contacts [3] Extended wear soft contacts

ps15b 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

ps15c 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
[1] [2] → INELIGIBLE

16. How did you hear about this study? **Mark all that apply.**

- ps16_sj_015 [] Sjögren's syndrome clinic ps16_od_015 [] Other doctor ps16_su_015 [] Support group/seminar
- ps16_de_015 [] Dentist ps16_we_015 [] Website/internet ps16_fr_015 [] Friend/relative
- ps16_rh_015 [] Rheumatologist ps16_ad_015 [] Advertisement (conference, journal, etc.) ps16_ot_015 [] Other
- ps16_op_015 [] Ophthalmologist (eye doctor)

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Eligibility

yes no Pending Read "Pending statement" and go to Willingness to Participate

ps17_016 17. Based upon screening, is the candidate eligible?..... [1] [2] [3]

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

ps17a_a_016 [1] Candidate is < 21 years of age (NO to question 1)

ps17a_b_016 [1] Candidate responded YES at least once to questions 2, 3c-5

ps17a_c_016 [1] Candidate gave all NO or NOT SURE responses to questions 6-11

ps17a_d_016 [1] Candidate responded YES at least once to questions 12-14 or NO to 15c

ps17a_e_016 [1] Candidate unwilling to request Physician Confirmation of RA/SLE Diagnosis (CANNOT OBTAIN to question 3ai or 3bi)

ps17a_f_016 [1] Unable to obtain Physician Confirmation of RA Diagnosis from MD (CANNOT OBTAIN to question 3ai)

ps17a_g_016 [1] Unable to obtain Physician Confirmation of SLE Diagnosis from MD (CANNOT OBTAIN to question 3bi)

Read "Willingness to Participate" and Go to item 17b

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".

ps17b_016 17b. Does candidate agree to participate in the study?..... [1] [2]

yes no 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?

yes no not sure If YES to ANY, complete Baseline Systemic Diagnoses Confirmation Form after contacting participant's physician

ps18_016 18. Thyroid disease..... [1] [2] [3]

ps19_016 19. Liver disease..... [1] [2] [3]

ps20_016 20. Kidney disease..... [1] [2] [3]

ps21_016 21. Lymphoma..... [1] [2] [3]

Read "Conclusion 3".

telephone in person

ps22_016 22. How was this interview conducted?..... [1] [2]



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Plate #013

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- UCSF ONLY -

ps23_013 23. Is your ethnic background Hispanic, Latino or other Spanish descent? yes no
 1 2

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

ps24_ca Caucasian/White/Middle Eastern ps24_af African-American/Black/Haitian

ps24_as Asian ps24_am American Indian/Native American/Alaskan Native

ps24_na Native Hawaiian/Pacific Islander ps24_ot Other

ps25 25. Date of final review of Participant Screening Questionnaire with participant:
dd mm yy

Staff Initials

Staff Signature and Date _____