



Study #021

Plate #440

Seq #005

Participant ID # [][] - [][][][] - [][]

Visit Date [][] [][] [][]
day month year

Follow-up Enrollment Status Form

- | | | yes | no | |
|-------|---|-------|-------|--|
| fes0a | 0a. Confirmed diagnosis of RA | [1] | [2] | |
| fes0b | 0b. Confirmed diagnosis of SLE | [1] | [2] | <i>unavailable /
indeterminate</i> |
| fes1 | 1. Focus score > 0 | [1] | [2] | [3] |
| fes2 | 2. Anti-SS-A positive | [1] | [2] | [3] |
| fes3 | 3. Anti-SS-B positive | [1] | [2] | [3] |
| fes4 | 4. Schirmer strip ≤ 5 mm in either eye | [1] | [2] | [3] |
| fes5 | 5. Tear break-up time < 10 seconds in either eye | [1] | [2] | [3] |
| fes6 | 6. Whole unstimulated salivary flow rate ≤ 0.5mL / 5 min. . . | [1] | [2] | [3] |

If YES to BOTH in box, pSS Case; if YES to BOTH in box AND YES to 0a or 0b, sSS Case

- | | | | | |
|--|--|-------|-------|-------|
| fes7 | 7. SICCA eye score ≥ 4 for either eye* | [1] | [2] | [3] |
| fes8 | 8. Focus score > 1.0 | [1] | [2] | [3] |
| *Review questions 1a-4 on Follow-up Eye Examination Form. If YES to one or more items, mark "unavailable/indeterminate" for SICCA eye score. | | | | |

fes9 9. Is the participant taking any anticholinergic drugs? [1] [2] [3]

- fes10 10. Enrollment Status
- [1] pSS Case - YES to 7 AND 8, and NO to 0a and 0b
 - [5] sSS Case - YES to 7 AND 8, and YES to 0a or 0b
 - [2] Level 2 Control - YES at least once to items 1-8 AND does not meet criteria for pSS, sSS or Level 1 Control
 - [3] Level 1 Control - NO to ALL items 1-8 or YES to ONLY 6 and 9
 - [4] Indeterminate - missing necessary criteria

Staff Initials [][] [][]

Staff Signature and Date _____