CPN MAY06-8-01 Case Report Form (CRF) Fax Cover Sheet

cancer prevention network

To: **QAS, Mayo Clinic-Rochester** Fax: **507-266-3722**
Phone: 507-284-4798

From: _____ Fax: _____

Pages attached including cover sheet: _____ Phone: _____

PID # _____ Date: _____

CRFs attached (please check all that apply):

Pre-Registration Visit:
- ❑ 1. Pre-registration
- ❑ 10. Clinical Lab Data – C-Reactive Protein
- ❑ 3. Screen Failure, if applicable

Prior to Registration/Randomization Visit:
- ❑ 11. Clinical Laboratory Data – Hematology
- ❑ 12. Clinical Laboratory Data – Blood Chemistry
- ❑ 13. Clinical Laboratory Data – Urine
- ❑ 28. Pregnancy Testing Results
- ❑ 7. Physical Exam
- ❑ 8. AE and Concomitant Meds Evaluation
- ❑ 9. Concomitant Medications
- ❑ 5. Symptom Assessment
- ❑ 4. Medical/Surgical History
- ❑ 16. Risk Assessment
- ❑ 19. Bronchial Biopsy Results
- ❑ 22. Biopsy Specimen Submission
- ❑ 23. Blood Specimen Submission

After Receiving Bronchoscopy Results:
- ❑ 3. Screen Failure

Registration/Randomization Visit:
- ❑ 2. Registration/Randomization
- ❑ 5. Symptom Assessment
- ❑ 29. Agent Label

Telephone Interview for (check one)
☐ Week 2 ☐ Month 2 ☐ Month 4 ☐ Month 5

- ❑ 15. Compliance – Phone Interview
- ❑ 24. Agent Interruption Continuation, if applicable
- ❑ 8. AE and Concomitant Medications Evaluation
- ❑ 9. Concomitant Medications, if applicable
- ❑ 20. Adverse Events, if applicable

Month 1 Visit:
- ❑ 14. Compliance
- ❑ 24. Agent Interruption Continuation, if applicable
- ❑ 8. AE and Concomitant Medications Evaluation
- ❑ 9. Concomitant Medications, if applicable
- ❑ 20. Adverse Events, if applicable
- ❑ 12. Clinical Laboratory Data – Blood Chemistry

Month 3 Visit:
- ❑ 14. Compliance
- ❑ 24. Agent Interruption Continuation, if applicable
- ❑ 8. AE and Concomitant Medications Evaluation
- ❑ 9. Concomitant Medications, if applicable
- ❑ 20. Adverse Events, if applicable
- ❑ 7. Physical Exam
- ❑ 11. Clinical Laboratory Data – Hematology
- ❑ 12. Clinical Laboratory Data – Blood Chemistry
- ❑ 13. Clinical Laboratory Data – Urine
- ❑ 29. Agent Label

Month 6 Visit or Early Termination:
- ❑ 14. Compliance
- ❑ 24. Agent Interruption Continuation, if applicable
- ❑ 10. Clinical Laboratory Data – C-Reactive Protein
- ❑ 22. Biopsy Specimen Submission
- ❑ 19. Bronchial Biopsy Results
- ❑ 23. Blood Specimen Submission
- ❑ 11. Clinical Laboratory Data – Hematology
- ❑ 12. Clinical Laboratory Data – Blood Chemistry
- ❑ 13. Clinical Laboratory Data – Urine
- ❑ 7. Physical Exam
- ❑ 8. AE and Concomitant Medications Evaluation
- ❑ 9. Concomitant Medications, if applicable
- ❑ 20. Adverse Events, if applicable
- ❑ 25. Biomarker Results – BAL
- ❑ 26. Biomarker Results – Immunohistochemistry
- ❑ 27. QOL Questionnaire: Was It Worth It?

Follow-up Phone Call: Prior to Reg/Rand for screen failures after bronch, < 30 days of Month 6, Early Termination, or Continued Follow-up for Adverse Events:
- ❑ 36. Follow-up Telephone Call
- ❑ 8. AE and Concomitant Meds Evaluation
- ❑ 20. Adverse Events, if applicable

Participant Complete and Off-Study with No Adverse Events:
- ❑ 29. Off Study
- ❑ 31. Verification

Any Time/As Needed:
- ❑ 34. Comments
- ❑ 3. Screen Failure
- ❑ 20. Adverse Events
- ❑ 24. Agent Interruption/Continuation
- ❑ 32. Death Report
- ❑ 33. Outcome of Pregnancy
- ❑ Other: Specify _____

- The following CRFs are required for individuals determined to be screen failures when no bronchoscopy was done: Pre-Registration CRF, Clinical Lab Data-CRP, Screen Failure, Verification, AE and Concomitant Medication Evaluation Form, and Adverse Events.
- The following CRFs are required for individuals who did have a bronchoscopy but were determined to be screen failures: Pre-Registration CRF, Clinical Lab Data –CRP, Screen Failure, Verification, Adverse Events and Concomitant Medication Evaluation, Adverse Events, Biopsy Specimen Submission, Bronchial Biopsy Results, Risk Assessment, and Follow up Telephone Call.
- For individuals who are determined to be screen failures after bronchoscopy, the Concomitant Medications CRF is also required if Adverse Events were reported on the Follow-up Telephone Call.

Revised 15 December 2010