Asthma Clinical Research Network
CIMA
NIH/NHLBI

TREATMENT FAILURE

Subject ID: __2__ ___ ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: __9__

Current Date: ___ ___ / ___ ___ / ___ ___
month   day   year

Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

| TXF_01 | 1. | Is this treatment failure visit replacing a regular scheduled visit? | ☐$_1$ Yes   ☐$_0$ No |

| TXF_01a | | If **Yes**, indicate visit number of scheduled visit | ___ |

| TXF_01b | | If **No**, indicate last regular visit completed | ___ |

| TXF_02 | 2. | Date treatment failure conditions started | ___ ___ / ___ ___ / ___ ___ <br> month day year |

| TXF_03 | 3. | Did the subject experience an FEV_1 value $\leq$ 80% of the value recorded at Visit 3? | ■$_1$ Yes   ☐$_0$ No |

| TXF_04 | 4. | Did the subject have an $FEV_1 \leq$ 40% predicted? | ■$_1$ Yes   ☐$_0$ No |

| TXF_05 | 5. | Did the subject experience a fall in pre-bronchodilator PEFR to $\leq$ 65% of baseline (baseline defined as the average AM or PM pre-bronchodilator PEFR recorded during study week 4, just prior to steroid withdrawal) on two out of three consecutive scheduled measurements? | ■$_1$ Yes   ☐$_0$ No |

6. Did the subject experience one of the following conditions?

| TXF_06a | 6a. | An increase in rescue inhaler use of $\geq$ 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours? | ■$_1$ Yes   ☐$_0$ No |

| TXF_06b | 6b. | Use of rescue inhaler $\geq$ 16 total puffs per 24 hours for a period of 48 hours? | ■$_1$ Yes   ☐$_0$ No |

| TXF_07 | 7. | Did the subject refuse to take study medications due to lack of satisfaction with treatment regimen? | ■$_1$ Yes   ☐$_0$ No |

8. Has the subject taken any of the following medications since the treatment failure conditions started?

TXF_08a	8a.	Inhaled or Oral Steroids	❏₁ Yes ❏₀ No
TXF_08b	8b.	Theophylline	❏₁ Yes ❏₀ No
TXF_08c	8c.	Beta-Agonist via nebulizer	❏₁ Yes ❏₀ No
TXF_08d	8d.	Cromolyn	❏₁ Yes ❏₀ No
TXF_08e	8e.	Tilade	❏₁ Yes ❏₀ No
TXF_08f	8f.	Ipratropium bromide	❏₁ Yes ❏₀ No

TXF_09

9. Is the subject a treatment failure? *If any of the shaded boxes are filled in, the subject is a treatment failure.*
☞ If Yes, please continue with the Treatment Failure data packet.

❏₁ Yes ▨₀ No