

TRIAL WITHDRAWAL CRF		
Serial number: _ _ _ _	Site: _ _ (AB, LE, LO, GP)	Subject number (IMP): _ _ _ _
Patient Initials: _ _ _ _	Researcher Initials: _ _ _	Date of THIS Visit: _ _ / _ _ / _ _

(Circle as appropriate)

1.	Has the participant withdrawn from:	Treatment Only	<i>(i.e. Placebo/Montelukast)</i>	0
		Trial	<i>(i.e. Treatment and Follow-Up)</i>	1

2.	Date of withdrawal	<table style="display: inline-table; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">Day</td> <td style="text-align: center; font-size: 8px;">Month</td> <td colspan="4" style="text-align: center; font-size: 8px;">Year</td> </tr> </table>							Day	Month	Year			
Day	Month	Year												

3.	Reason for withdrawal <i>(Circle all that apply)</i>	Eligibility criterion no longer met (Specify: _____)	1
		Death of participant (SAE no. _____)	2
		Other adverse event (AE/SAE no. _____)	3
		Deterioration of pre-existing medical condition	4
		Poor adherence to treatment	5
		Perceived lack of efficacy of medication	6
		Unable to locate participant/carer	7
		Other (Specify: _____)	8

4.	Withdrawal decision initiated by: <i>(Circle all that apply)</i>	Chief Investigator (CI)	1
		Principal Investigator (PI)	2
		Referring Investigator	3
		Carer	4
		Participant	5
		Other (Specify: _____)	6

5.	Would the PI have independently recommended treatment withdrawal ?	No	0
		Yes	1

6.	Permission given to use data collected:	No, use of all data collected to date denied	1
		Yes, partial permission to use data up to withdrawal (Specify: _____)	2
		Yes, permission to use all data up to withdrawal	3
		Yes, permission to collect and use all follow-up data	4

7.	Treatment code broken: <i>(Not unless absolutely necessary)</i>	No	0
		Yes (Emergency Unblinding Request no. _____)	1

8.	Signature of Researcher	
	Signature of Principal Investigator	