

A3.31 Withdrawal Form

1.	Has the participant withdrawn from:	Treatment Only	<i>(ie Placebo / Mirtazapine / Sertraline)</i>	0														
		Trial	<i>(ie Treatment and Follow-Up)</i>	1														
2.	Brief description of the reason for withdrawal <i>(attach additional sheets if necessary)</i>																	
3.	Date of withdrawal	<table style="margin-left: auto; margin-right: auto;"> <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> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">Day</td> <td style="text-align: center;">Month</td> <td colspan="3"></td> <td style="text-align: center;">Year</td> <td></td> </tr> </table>										Day	Month				Year	
Day	Month				Year													
4.	Reason for withdrawal <i>(Circle all that apply)</i>	Eligibility criterion no longer met <i>(Specify: _____)</i>		1														
		Death of participant <i>(SAE no. _____)</i>		2														
		Other adverse event <i>(AE / SAE no. _____)</i>		3														
		Deterioration of pre-existing medical condition		4														
		Poor adherence to treatment		5														
		Perceived lack of efficacy of medication		6														
		Unable to locate participant		7														
		Unable to locate a carer		8														
		Other <i>(Specify: _____)</i>		9														
5.	Withdrawal decision initiated by: <i>(Circle all that apply)</i>	Chief Investigator		1														
		Principal Investigator		2														
		Referring Investigator		3														
		Carer		4														
		Participant		5														
		Other <i>(Specify: _____)</i>		6														
6.	Would the Principal Investigator have independently recommended withdrawal from treatment	No		0														
		Yes		1														
7.	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 <i>(Specify: _____)</i>		2														
		Yes, permission to use all data up to withdrawal		3														
		Yes, permission to collect and use all follow-up data		4														
8.	Treatment code broken: <i>(Not unless absolutely necessary)</i>	No		0														
		Yes <i>(Emergency Unblinding Request no. _____)</i>		1														
9.	<i>Signature of Research Worker:</i>	<i>Signature of Principal Investigator</i>																