## HTA-SADD Full Trial Protocol: Version 2.5 (14/9/2009)

## A3.1 Additional Diagnostic Questions

Most of the questions required to make a diagnosis of depression based on DSM-IV (TR) criteria for a Major Depressive Episode and/or Olin (2002)'s Diagnostic Criteria for Depression of Alzheimer's Disease have already been asked as part of the CSDD, NPI and Medical History.

I would like to ask you some additional questions about (*participant*)'s mood so that we can establish whether he/she meets formal research diagnostic criteria for depression.

1.	How long have his/her	Less than one month	1
1.	current symptoms of depression lasted?	Between one and two months	2
		Between two and six months	3
		Over six months	4
2.	Have his/her <u>current</u> symptoms of depression lasted for a period of at least two weeks at any time since the symptoms began?	No	0
		Yes	1
		Don't know	88
	Comments:		
3.	Have his/her <u>current</u>	No	0
5.	symptoms of depression been present solely while he/she has been very drowsy?	Yes	1
		165	L
		Don't know	88
4.	Has he/she been bereaved during the last year? (i.e. lost a loved one)	No	0
		Yes	1
		Don't know	88
	If so, what was the effect of the bereavement on the participant?		
5.	How many times has he/she been depressed before?	None, this is the first time	0
		Once before	1
		Twice before	2
		Many times before	3
		Don't know	88
6.	Does he/she have a reduced ability to think, concentrate or make decisions nearly every day?	No	0
		Yes	1
		Don't know	88

I would now like to ask you some additional questions about (*participant*)'s cognitive state so that we can establish the extent to which the memory problems may be attributed to vascular changes.

7.	Did the memory problems symptoms start gradually or suddenly?	Gradually	0
		Suddenly	1
		Don't know	88
8.	Did the memory problems symptoms get worse steadily over time or in stages?	Steadily over time	0
		In stages	1
		Don't know	88
9.	Are the memory problems symptoms much the same from day-to-day or are some days much worse or better	Much the same from day-to-	0
		Some days much worse/better	1
		Don't know	88
10.	Are the memory problems symptoms worse in the evenings?	No	0
		Yes	1
		Don't know	88
11.	Are his/her moods very changeable? Does he/she become tearful without any reason?	No	0
		Yes	1
		Don't know	88
12.	In terms of ( <i>participant</i> )'s personality, has their character changed or do they seem to be much the same person?	Character changed	0
		Much the same	1
		Don't know	88
13.	Is ( <i>participant</i> ) weaker on one side compared to the other?	No	0
		Yes	1
		Don't know	88

NOTE: Questions 7 to 13 would only be asked during the baseline assessment visit.