ONLY to be used with prior agreement of SEARCH administrator when SENTRY data-entry system is NOT available

Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine — SEARCH

FINAL FOLLOW-UP FORM BACK-UP

Study reference: ___ – ____

Forename:

Surname:

Yes / No

☐ ☐ Follow-up in clinic?

☐ ☐ Currently hospitalised?

Alterations to contact details:

Address:

Postcode:

Daytime telephone:

Home telephone:

1. SERIOUS ADVERSE EVENTS (SAE) SINCE LAST FOLLOW-UP

Possible	No		First **DATE** of event Day / Month / Year	**NIGHTS** in hospital	
☐	☐	Heart attack	/ /		
☐	☐	Hospitalisation for angina	/ /		
☐	☐	Coronary artery bypass	/ /		
☐	☐	Coronary	/ /		
☐	☐	Other arterial surgery/angioplasty	/ /		
☐	☐	Stroke	/ /		
☐	☐	Pulmonary embolus	/ /		
☐	☐	Cancer	/ /		& site:
☐	☐	Other hospitalisation or SAE	/ /		& specify:
☐	☐	Other hospitalisation or	/ /		″
☐	☐	Other hospitalisation or SAE	/ /		″

2. OTHER EVENTS SINCE LAST FOLLOW-UP

Yes / No

☐ ☐ Unexplained muscle pain or weakness (i) severity: ☐ Mild ☐ Moderate ☐ Severe

(ii) site(s):

☐ ☐ Adverse events considered **likely** to be due to study treatment. If **Yes**, specify:

3. REGULAR NON-STUDY TREATMENT

Record the names (not doses) of all prescription and "over the counter" treatments that are being taken **regularly** , including any vitamin supplements

4. STUDY TREATMENT

Approximate percentages of scheduled study treatments taken in last week?

	90%+	80-89%	10-79%	<10%
Simvastatin 20mg/placebo (tan):	☐	☐	☐	☐
Simvastatin 80mg/placebo (pink):	☐	☐	☐	☐
Supplement/placebo (white):	☐	☐	☐	☐

5. BLOOD PRESSURE

☐ Systolic blood pressure

☐ Diastolic blood pressure

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6. HEARING QUESTIONNAIRE

		✓
Q1.	**Nowadays, do you usually wear a hearing aid?**	
	No	☐
	No, but have tried one	☐
	Yes, some of the time	☐
	Yes, most of the time	☐
	All following questions should be answered as if the participant does NOT use a hearing aid	
Q2.	**Do you have any difficulty with your hearing?**	
	No	☐
	Yes	☐
Q3.	**<u>In the last 12 months</u> have you been to your own doctor (GP) or referred to a hospital about problems with your hearing?**	
	No	☐
	Yes	☐
Q4.	**Do you find it very difficult to follow a conversation if there is background noise (such as TV, radio, children playing)?**	
	No	☐
	Yes	☐
Q5. a)	**How well do you hear someone talking to you when that person is sitting… …on your <u>RIGHT SIDE</u> in a quiet room?**	
	With no difficulty	☐
	With slight difficulty	☐
	With moderate difficulty	☐
	With great difficulty	☐
	Cannot hear at all	☐
b)	**…on your <u>LEFT SIDE</u> in a quiet room?**	
	With no difficulty	☐
	With slight difficulty	☐
	With moderate difficulty	☐
	With great difficulty	☐
	Cannot hear at all	☐
Q6.	**Do you have difficulty following TV programmes at a volume others find acceptable, without any aid to hearing?**	
	No	☐
	Yes, slight difficulty	☐
	Yes, moderate difficulty	☐
	Yes, great difficulty	☐
Q7.	**Do you have difficulty having a conversation with several people in a group?**	
	No	☐
	Yes, slight difficulty	☐
	Yes, moderate difficulty	☐
	Yes, great difficulty	☐
Q8.	**<u>Nowadays</u>, how much does any difficulty in hearing worry, annoy or upset you?**	
	Do not have hearing difficulty	☐
	Not at all annoying	☐
	Slightly annoying	☐
	Moderately annoying	☐
	Severely annoying	☐
Q9.	**<u>Nowadays</u>, do you <u>ever</u> get noises in your head or ears (tinnitus) which usually last longer than five minutes?**	
	No, never	☐
	Some of the time	☐
	Most or all of the time	☐

7. COGNITIVE FUNCTION TEST

1. **Question: "What is today's date?"** Day **Yes** ☐ **No** ☐ Month **Yes** ☐ **No** ☐ Year **Yes** ☐ **No** ☐
   Indicate Yes or No according to whether each part of the date was correctly given

2. **Question: "What season are we in?"** Correct answer given? **Yes** ☐ **No** ☐

3. **Question: "What day of the week is it today?"** Correct answer given? **Yes** ☐ **No** ☐

4. **Question: "What is your age?"** Correct answer given? **Yes** ☐ **No** ☐

5. **Question: "What is your home phone number?"** Correct answer given? **Yes** ☐ **No** ☐
   (To be correct the patient must provide the full number including any area code)

6. **"I'm going to read you a list of 10 words. Please listen carefully and try to remember them. I'm then going to ask you to tell me as many words as you can, in any order."** (After reading words, please ask patient to repeat them).

   Tick appropriate box to register each word correctly recalled:

Cabin	☐	Silk	☐	Pillow	☐	Chest	☐	Whip	☐
Elephant	☐	Watch	☐	Pipe	☐	Theatre	☐	Giant	☐

7. **"Please take 7 away from 100. Now continue to take 7 away from the answer until I ask you to stop."** (Go to next question if the patient stops)

	1	2	3	4	5
Answer	93	86	79	72	65
Patient answer					

8. **Question: "What do people usually use to cut paper?"** Correct answer "scissors" given? **Yes** ☐ **No** ☐

9. **Question: "Please count backwards from 20 to 1"** Score "Yes" if succeeded at first attempt without any mistakes. Correct answer given? **Yes** ☐ **No** ☐

10. **Question: "What is the prickly green plant called that is found in the desert?"** Correct answer: "Cactus". Correct answer given? **Yes** ☐ **No** ☐

11. **Question: "Please say 'Methodist Episcopal'"** Score yes if repeated correctly. Correct answer given? **Yes** ☐ **No** ☐

12. **Question: "Who is the reigning monarch now?"** Correct answer: "Queen Elizabeth", "Elizabeth" or "Queen Elizabeth the second". Correct answer given? **Yes** ☐ **No** ☐

13. **Question: "Who is the prime minister now?"** Score "Yes" if surname correct. Correct answer given? **Yes** ☐ **No** ☐

14. **Question: "What is the opposite of East"** Correct answer: "West". Correct answer given? **Yes** ☐ **No** ☐

15. **"Please repeat the 10 words I read earlier"** Tick appropriate box to register each word correctly recalled:

Cabin	☐	Silk	☐	Pillow	☐	Chest	☐	Whip	☐
Elephant	☐	Watch	☐	Pipe	☐	Theatre	☐	Giant	☐

16. **"I am going to give you a category and I want you to name, as fast as you can, all of the things that belong in that category. For example, if I say 'articles of clothing', you could say shirt, tie or hat. Can you think of any other articles of clothing?".** After you are satisfied that the patient has understood and has given two words naming articles of clothing, say: **"That's fine. I want you to name all of the things that belong to another category, this is 'animals'. Any type of animal is ok: farm animals, birds, fish, insects, any kind of animal will do. You will have one minute. Ready, go!"** (Start timing)

   Score one for each animal mentioned.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20

21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40

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8. HEARING TEST

Please tell patient:

I am going to test your hearing by measuring the faintest sounds that you can hear. As soon as you hear a sound, raise your finger. Keep it raised as long as you can hear the sound, no matter which ear you hear it in. Lower your finger as soon as you think you no longer hear the sound.

It is important that you keep as quiet as possible in order to hear the faintest sounds. It will help, therefore, if you breathe quietly through your mouth. Also, hold the headphone cord away from your body, like this (demonstrate). No matter how faint the sound, raise your finger when you think you hear it, and lower it when you think you do not hear it any longer.

	Left		Right
Left ear @ 1 kHz	☐	Right ear @ 1 kHz	☐
Left ear @ 4 kHz	☐	Right ear @ 4 kHz	☐

Measure left side then right side. Enter 95 if unable to hear at 90. Enter # only if a value definitely cannot be assessed.

9. BLOOD SAMPLES

Yes	No	
☐	☐	Green 10ml blood sample taken?
☐	☐	Grey 4ml blood sample taken?
☐	☐	Pink 10ml blood sample taken?

BEFORE the patient leaves the clinic, telephone the coordinating centre office on 01865 743870 and provide the information recorded on this form (N.B. Any response that is changed should be crossed out and initialed)

Signature of clinic nurse: ☐

& **PRINTED** name: ☐

Today's date: ☐☐/☐☐/☐☐☐☐
Day Month Year

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