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

FOLLOW-UP FORM BACK-UP

Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine

SEARCH

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 angioplasty	/ /		
☐	☐	Other arterial surgery/angioplasty	/ /		
☐	☐	Stroke	/ /		
☐	☐	Pulmonary embolus	/ /		
☐	☐	Cancer	/ /		& site:
☐	☐	Other hospitalisation or SAE (see back of form)	/ /		& specify:
☐	☐	"	/ /		"
☐	☐	"	/ /		"

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 (see back of form)

4. STUDY TREATMENT

		90% +	80-89%	10-79%	<10%
Approximate percentages of scheduled study treatments taken in last week?	Simvastatin 20mg/placebo (tan):	☐	☐	☐	☐
	Simvastatin 80mg/placebo (pink):	☐	☐	☐	☐
	Supplement/placebo (white):	☐	☐	☐	☐

		Continue	Stop temporarily	Stop permanently
Are study treatments to continue after this study follow-up?	Simvastatin/placebo (tan and pink):	☐	☐	☐
	Supplement/placebo (white):	☐	☐	☐

If any of the study treatments are stopped, give one or more reasons:

☐ Patient wishes to stop treatment ☐ Patient cannot attend clinic ☐ Contraindicated drug started ☐ Abnormal ALT or CK

☐ Other; specify:

5. BLOOD SAMPLE, DRUG SUPPLY & FOLLOW-UP

Yes / No

☐ ☐ Blood sample taken: **MUST** be **Yes** if study simvastatin is to continue

☐ ☐ Labelled study treatment dispensed; and if **Yes**, specify pack reference number: ___|___|___|___|–|___|___|

☐ ☐ Next follow-up in clinic? If **No**, is it to be via: ☐ Telephone ☐ GP

BEFORE the patient leaves the clinic, telephone the coordinating centre office on 01865-404870 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)

• SEND THIS FORM TO COORDINATING CENTRE IMMEDIATELY AFTER THE CLINIC •

DEFINITIONS: FOLLOW-UP FORM

Serious Adverse Events (SAEs)

Serious adverse events are those medical occurrences which result in death or are life-threatening, produce a persistent or significant disability, require in-patient hospitalisation or the prolongation of existing hospitalisation, are cancer or congenital abnormality, or are judged to jeopardise the patient or to require intervention to prevent any of the other outcomes listed. All such events are to be recorded on this form.

Any SAEs that are **believed** by the patient or study nurse **to be due** to study treatment should have the reason(s) for believing this recorded on this form, and should also be reported **immediately** after the clinic session by telephoning the coordinating centre 24-hour service on 0800-585323 (as should any accidental or intentional overdose of study treatment).

Contraindicated treatments (and brand names)

Contraindicated non-study cholesterol-lowering treatments:

- **Statins:** atorvastatin (Lipitor), cerivastatin (Lipobay), fluvastatin (Lescol), lovastatin (Mevacor), pravastatin (Lipostat), simvastatin (Zocor);
- **Fibrates:** bezafibrate (Bezalip), ciprofibrate (Modalim), clofibrate (Atromid-S), fenofibrate (Lipantil), gemfibrozil (Lopid);
- **High-dose niacin:** daily dose of nicotinic acid over 1 gm, or any dose of acipimox (Olbetam) or nicofuranose (Bradilan).

Other contraindicated treatments:

- **Cyclosporin** (Neoral, Sandimmun);
- **Nefazodone** (Dutonin).

N.B. If the patient has been prescribed non-study statin, fibrate, high-dose niacin, cyclosporin or nefazodone then the study simvastatin tablets MUST be stopped, but study vitamin/placebo tablets may still be continued.
