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

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

RANDOMISATION FORM BACK-UP

Study reference: ☐☐☐-☐☐☐☐

Forename: ☐

Surname: ☐

Alterations to contact details:

Address: ☐

Postcode: ☐

Daytime telephone: ☐

Home telephone: ☐

1. CLINICAL EVENTS DURING RUN-IN

Yes	No/unsure	
☐	☐	Myocardial infarction, hospitalisation for angina or CABG/PTCA
☐	☐	**New UNEXPLAINED** muscle pain or weakness considered to be significant
☐	☐	Other serious adverse events (SAE:see over). If **Yes**, specify (and, if believed to be due to study treatment, give reasons):

2. LIKELY NON-COMPLIANCE

Yes	No/unsure	
☐	☐	Non-compliant with Run-in treatment (i.e. Approx. <90% of scheduled treatment taken)
☐	☐	Patient reluctant to continue in the study
☐	☐	Likely problems with attending regular clinics
☐	☐	CABG/PTCA planned in about the next 3 months
☐	☐	Other reasons for serious concern about long-term compliance. 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

Is the patient regularly taking a contraindicated drug (see back of form)?

Yes	No/unsure		Yes	No/unsure		Yes	No/unsure	
☐	☐	Non-study statin	☐	☐	Cyclosporin	☐	☐	Methotrexate
☐	☐	Fibrate or high-dose niacin	☐	☐	Nefazodone	☐	☐	Non-study folic acid over 200μg daily

N.B. Short-term use of systemic azol antifungals or macrolide antibiotics is not a reason for exclusion (see back of form)

4. ELIGIBILITY

Must be **No/unsure** to all questions above (except that "Other SAEs" can be **Yes** if **NOT** believed to be due to study treatment and **NOT** cancer)

Yes	No	
☐	☐	Is the patient **definitely** (eligible and) willing to continue?
☐	☐	Blood samples taken? **MUST** be **Yes** if patient is to be randomised.

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)

5. RANDOMISATION

Record the Randomisation pack number and Follow-up appointment allocated by the telephone service

Pack number: ☐☐☐☐☐-☐☐☐

Next appointment: ☐ (Day of week) ☐☐/☐☐/☐☐ (Day Month Year) ☐☐:☐☐ (Hour Min) am/pm

Signature of clinic nurse: ☐

& **PRINTED** name: ☐

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

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

DEFINITIONS: RANDOMISATION 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 cholesterol-lowering treatments:

— **Non-study statin:** 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).

N.B. Patients do **not** need to be excluded for using other cholesterol-lowering treatments, such as lower doses of niacin, probucol (Lurselle), cholestyramine (Questran), or colestipol hydrochloride (Colestid).

Other contraindicated treatments:

— **Cyclosporin** (Neoral, Sandimmun);
— **Nefazodone** (Dutonin);
— **Methotrexate** (Maxtrex, Methotrexate);
— **Non-study folic acid over 200 μg daily:** Most multivitamin preparations contain lower doses of folic acid, and use of these (or of non-study vitamin B_{12}) is **not** a reason for exclusion.

Other treatments (and brand names)

— **Systemic azol antifungals:** fluconazole (Diflucan), itraconazole (Sporanox), ketoconazole (Nizoral), miconazole (Daktarin);
— **Systemic macrolide antibiotics:** erythromycin (Arpimycin, Erymax, Erymin, Erythrocin, Erythroped, Ilosone, Tiloryth), clarithromycin (Klaricid).

N.B. At the Randomisation visit, planned short-term use of systemic azol antifungals or macrolide antibiotics is **not** a reason for exclusion. Instead, the patient should be randomised and advised not to start taking the study simvastatin until after stopping the course of systemic azol antifungal or macrolide antibiotic. (Topical use of azol antifungals or macrolide antibiotics is **not** a reason for delaying study treatment.)