

## CII Autograft Trial – Quality of Life Study Standard Operating Procedure – Overview

### Randomisation

Patient in centre – eligibility criteria for study met

Randomise (via Oxford) The randomisation form reminds the centre to enter the given Trial Number onto a baseline QoL Questionnaire and give it to the patient with a return envelope.

Leiden notified of the randomisation by Oxford

*Centres hold small supply of Baseline questionnaires. When down to last one centre should request a further supply from central co-ordinator or download more in readiness.*

*Each country should have a central co-ordinator – otherwise this function should be performed by the data centre in Leiden. The central co-ordinator should record receipt of the patient's form, arrange for any comments to be translated before sending on to the data centre in Leiden, and send Investigator Forms out to enquire about any missing data.*

### **Follow up. (4,8,12,24,36,48 months)**

The data centre in Leiden will send a reminder to the central co-ordinator at least 1 month before the follow up is due.

Central co-ordinators will produce a supply of follow up forms, or instruct the centres to produce the appropriate forms themselves.

Reply paid envelopes addressed to the co-ordinating centre for the country will be supplied by means decided between the central co-ordinator and the centres for each country.

When alerted by Leiden they will either send a questionnaire and a reply paid envelope for each patient to the appropriate centre, making sure they send the right questionnaire and indicating the time point.(4 and 8 months have a separate questionnaire, then use the annual one for 12,24,36 and 48 months), or tell the centre which follow ups are due so that the correct forms can be produced in time.

The questionnaire will be either a) given to the patient at a clinic visit or b) posted to the patient if they are not attending at that time-point. The patient will then return the completed questionnaire in the envelope supplied.

The central co-ordinator will record receipt of the questionnaire, arrange for any comments to be translated, send it on to Leiden, and note any questionnaires which have not been returned within a month of the due date and ask the centre to chase them up or to complete an Investigator's form giving reasons why the questionnaire is missing (eg patient refusal, too ill, died etc)

### **Data monitoring.**

Data should be sent to Janis Homewood on a six monthly basis for monitoring progress. *(Need to discuss the best way of doing this)*