

THE OSCAR TRIAL CONSENT PROCESS - Scotland

REC: 07/MRE00/73 / Version 2 – 3 Sept 07

Patient fulfils eligibility criteria but does not have capacity to consent to trial Has the patient a Welfare Guardian or Nearest Relative?	
YES	NO
<div style="display: flex; align-items: center; margin-bottom: 10px;"> ↓ • </div> <p>Is this person willing and able to take on the responsibilities of Welfare Guardian/Nearest Relative (WG/NR) in this situation?</p> <p style="text-align: center;">If No</p> <p>If Yes Explanation to be given in person and questions encouraged. Information sheet to be provided. Written consent to be signed by WG/NR If WG/NR not present in person, verbal consent to be obtained by telephone using 'Welfare Guardian/Nearest Relative <i>Verbal Consent</i>' form. Written consent to be obtained as soon as possible if practical Local investigators will ensure that the WG/NR receives a copy of the consent form.</p>	<p>The patient cannot be entered into the trial</p>
The quality of consent should be ascertained from the responses given. Questions should be encouraged, and an opportunity to clarify information provided.	

At ICU discharge or before when the patient has regained capacity:

Give the patient a copy of the *Patient* information sheet (retrospective information), and talk them through it.

Inform the patient that after ICU discharge being in the trial will involve receiving one questionnaire to their home six months after their ICU treatment, and another at 12 months. (We may also send a further 3 questionnaires to them at six month intervals.) The questionnaire will ask how their breathing is and about their general well-being.

A freepost (no stamp required) envelope will be provided with the questionnaire so there is no cost to the patient.

Ask the patient if they would be willing to consent themselves to continue in the trial.

If they agree

Ask them to sign a consent to continue form to show agreement.

Once signed, provide them with a copy.

If they decline

No questionnaires will be sent to the patient.

A Withdrawal From Trial sheet should be completed.