

THE OSCAR TRIAL CONSENT PROCESS - England and Wales

ENGLAND AND WALES

Does the patient have a family member/next of kin/friend/carer who knows them well who:

- (a) is interested in the patient's welfare and best interests,
- or
- (b) is an attorney acting under a Legal Power of Attorney
- or
- (c) is a court appointed deputy who could act as a 'Personal Consultee'?

None of the above should be paid to look after the patient/be in their paid employment, i.e. paid carers **cannot** act as Personal Consultee.

Yes

No

Does this person live a long distance away?

Yes

No

(1) Is this person willing to take on the responsibilities of a 'Personal Consultee'? (Give an opinion on whether their relative/ next of kin/friend might want to take part in the OSCAR trial.)

And

(2) Are they able to understand the information provided about the OSCAR trial?

Yes

No

Do they wish to nominate another family member/next of kin/friend/carer to take on the role of Personal Consultee?

Yes

No

Personal Consultee : Give the consultee the trial information sheet. Talk them through it and answer any questions.

You should ask what, in their opinion, the patients' wishes and feelings about taking part in the study would be if they had the capacity to make the decision for themselves.

To aid their decision making process you may ask them to think about whether the patient had previously expressed specific or general support for research of this type. It may also be helpful to remind the consultee that he or she is NOT being asked for their OWN views on participation in the study or research in general, but their relatives' views. They need to set aside their own views and consider what the patients' views are.

- If they agree their relative can go into the study: ask them to sign a consultee form to show agreement. Once signed, provide them with a copy.
- If they advise you that in their opinion the patient would have declined to take part: the patient cannot be entered into the trial.

If the consultee cannot attend the ICU consider taking agreement over the telephone using the oral form.

Consider
Oral
agreement

A Nominated Professional Consultee in your Trust should be contacted.

They, after reviewing the trial information, will give their opinion on the patients entry into the trial. This person may still wish to talk to the relative who lives away before they make their decision.

Ask your Trust for details of who you can approach to take on this role.

The family member/next of kin/friend/carer can request a Nominated Professional Consultee be involved.

Local arrangements apply as in the box above.

Nominated Professional Consultee: Provide trial information sheet. Answer any questions.

The consultee will inform you of their decision:

- If they agree the patient can go into the study: ask them to sign a Consultee form to show agreement. Once signed, provide them with a copy.
- If they advise you that the patient cannot take part: the patient cannot be entered into the trial.

At ICU discharge or when the patient has regained capacity:

Give the patient a copy of the information sheet that was given to their relative and talk them through it. Explain that their relative gave an opinion as to whether they thought they would take part in the research if they could consent for themselves.

Inform them 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 form to show agreement.

Once signed, provide them with a copy.

If they decline

No questionnaires will be sent to the patient.

A Withdrawal sheet should be completed.