Standard Operating Procedure (SOP)

Patient Screening and Informed Consent Procedures

SOP 004

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Scope

- This document describes how to screen potentially eligible patients for inclusion in the OPTIMISE II trial and obtain written informed consent.

How to screen?

- Only staff who have been trained according to Good Clinical Practice (GCP) guidelines and with delegated responsibility by the Principal Investigator (PI), as per the delegation log, can conduct this task.
- Patients can be identified from pre-admission clinic lists, operating theatre lists and by communication with the relevant nursing/research medical staff.
- Patients should be screened for eligibility according to the inclusion and exclusion criteria detailed in the protocol.
- Not all patients will meet the inclusion criteria. In these cases it is not necessary to record this on the Screening Logs (Investigator Site File, section 3). Only patients who are identified as being eligible but **not** randomised should be recorded in the Screening Log. The reason for exclusion should be included on the Screening Log.
- Patients who are identified as being eligible and **are** randomised should also be recorded in the Screening Log.
- It is recognised that not every patient undergoing surgery can be screened for inclusion in to the OPTIMISE II trial.
- It is recognised that some eligible patients may be missed, e.g. owing to time pressures. However, the Screening Log may help to identify possible sources of bias in participant inclusion, or changes which could increase the overall recruitment rate.

Completion of the screening log

- Details required include: date of screening, participant initials, date of birth, gender and whether the patient was randomised into OPTIMISE II (Y/N).
    - if Yes, complete allocated Trial ID.
    - if No, provide the reason why the patient was not randomised.

Providing information to potential participants

- All eligible patients asked to consider taking part in the trial should be given the fullest possible information about the research**, presented in a way that they can understand**. This **must** include (but is not limited to) the current version of the Patient Information Sheet (PIS) approved by the Research Ethics Committee (you can check you have the correct version by contacting the OPTIMISE II team at the Trials Office). The information provided must include:
    I. Information about possible benefits and risks.
    II. Informing the patient that he or she may not benefit from the research.
    III. Evidence that a Research Ethics Committee has approved the research.
    IV. Informing the patient that participation is voluntary and that he or she can withdraw at any time without providing a reason and without prejudicing future medical care.
- The patient should be invited and encouraged to ask questions about the research, which should be answered to the best ability of the person obtaining consent. If additional information is needed to answer questions to the patient's satisfaction, then this should be obtained prior to completion of the consent process.
- Potential participants should be given enough time to read the information about the research. Where possible this period of time would be at least 24 hours. The Research Ethics Committee recognises and agrees that by the nature of current NHS procedures, patients often undergo surgery on the day of hospital admission or on an emergency basis. In these circumstances, the patient should still be allowed sufficient time to understand what participation involves and ask questions about this.
- The patient should be provided with a contact point where he or she may obtain further information about the trial.

- Patients must provide written informed consent in order to participate in the OPTIMISE II trial. This should be done using the OPTIMISE II trial consent form (ensure that you are using the currently approved version by contacting the OPTIMISE II team at the Trials Office).
- Consent forms should be printed out on your local hospital headed paper, with a version number and date, identifying the unit/department conducting the research. The information on this documentation as sent to you by the OPTIMISE II Trial team should not be amended.

Obtaining written informed consent

- Informed consent must be obtained before the initiation of any trial related procedures, tests or treatments as required by the trial protocol.
- Only the Principal Investigator, and staff authorised on the Delegation Log are allowed to obtain informed consent from participants. This must be a healthcare professional with an understanding of the OPTIMISE II trial intervention, and this would most often be a doctor or nurse with the relevant experience.
- An individual must not be pressured or coerced into participation in the trial.
- The person obtaining informed consent must ensure the patient:
    - Has fully understood what they are consenting to.
    - Is aware that they have the condition which determines eligibility of the patient to enter the trial.
    - Is away they may receive either the trial intervention or usual care, and fully understands the implications of decisions that may be made within the course of the research.
- If there is any doubt regarding the patient's capacity to give or withhold informed consent, they must not be randomised.
- The participant's name and trial ID should be checked to ensure that they are correct and to ensure that the participant has received all appropriate documentation (PIS and any other relevant trial information).
- The consent form must be signed and dated by the patient and countersigned by the person obtaining informed consent; this should be done in each other's physical presence. Where boxes need to be initialled, the patient must complete each box.
- Verbal consent is **not** sufficient for participation.

After consent has been obtained

- Once all parties have signed and dated the consent form, a copy of the information sheet and consent form is given to the patient and a further copy will be filed in their medical notes. The original signed copy of the consent is kept in the OPTIMISE II Investigator Site File (Section 3). **A patient's signed consent form should be kept regardless of how far the participant proceeds in the trial.**
- The signed consent forms **must not** be stored together with the Case Report Forms (CRFs).
- Note that Research Ethics Committees pay close attention to the informed consent process as described in the ethics application; this is an important factor in informing their decision to give a favourable opinion for the trial to go ahead. Any deviation from the approved informed consent process must immediately be reported in writing to the Optimise II trial team.
- Sites should write to the General Practitioner (GP) of all participating patients, using the current approved OPTIMISE II GP letter (ensure that you are using the currently approved version by contacting the Trials Office) on your local hospital headed paper. As with the PIS and consent forms, the information contained within these as provided by the OPTIMISE II trial team should not be altered.