Standard Operating Procedure

Eligibility & Informed Consent

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1 Purpose

1.1 To provide guidance on the eligibility and consent procedures for the PROTECT platform.

2 Eligibility and pre-screening

2.1 Potentially eligible participants will be pre-screened for eligibility by members of the direct care team.

2.2 Pre-screening includes reviewing the medical records, medical imaging, test results and operating theatre/clinic/scheduling lists.

2.3 Research delivery staff at each recruiting centre should be considered part of the direct care team.

2.4 All patients who are approached for inclusion should be recorded on the screening log.

2.5 Following pre-screening and prior to approaching potentially eligible patients (verbally or face to face) the Principal Investigator (PI) or delegate should add a note in the patient's medical records confirming that the patient has met the eligibility criteria and that they can be approached for the study. For CTIMP comparisons this is required to be completed by the PI or medically qualified delegate.

3 Informed Consent

3.1 Informed consent will be obtained after pre-screening but before the participant undergoes any procedures that are specifically for the purposes of the study and are outside routine care at participating sites.

3.2 Where possible participants should be given 24 hours to consider the study after they are initially approached and before they give consent. This should be documented in the participant's medical records.

3.3 For CTIMP comparisons, if consent is obtained by a research nurse or non-medically qualified member of the team, it is expected that a medically qualified doctor who is part of the trial team, is available during or following the consent process if the participant requests further discussion regarding the medical care they will receive in relation to the

trial. The PI or medically qualified doctor will need to verify the informed consent form has been completed correctly in a timely manner.

3.4 For non-CTIMP comparisons, consent does not require verification by the PI.

3.5 The consent process may either use electronic (eConsent) or paper consent, with eConsent the preferred method.

3.6 The consent process can be face-to-face or using a locally approved remote method.

3.7 Where participants have not been contacted face-to-face, the signed consent form will be returned via electronic methods or by post and countersigned by an appropriate member of the research team.

3.8 When using eConsent, the form may be completed on a computer, smartphone or tablet/electronic device. Consent will be recorded using an electronic signature generated either by using a finger or stylus tracing across a device or using a mouse to drag a cursor across the screen. All methods should be analogous to a traditional pen.

3.9 A copy of the Patient Information Sheet (PIS) and fully signed copy of the Informed Consent Form (ICF) will be given to the patient and a copy filed in their medical notes. If an electronic health record is used, documents will be uploaded to the electronic health record.

3.10 If using paper consent forms, the original signed copy will be kept in the Investigator Site File. If using eConsent a copy should be retained in the Investigator Site File. A patient's signed consent form should be kept, regardless of withdrawal.

3.11 This consent process should be documented in the patients' medical records prior to carrying out any trial related procedures.

3.12 The table below is an example of how the eligibility can be recorded in the patients' medical note by the research team.

Inclusion criteria	**Has criteria been met?**
Patients aged 18 years and over	Y- (please specify how)
Exclusion criteria	**Has criteria been met?**
Inability or refusal to provide informed consent	N - (please specify how)

4 Reading, writing and translation

4.1 If a participant is unable to read or sign the consent form but has capacity to give consent, this can be provided on the participant's behalf by a witness. A statement should be included in the consent form explaining that the participant understood the information and informed consent was given freely.

4.2 If translation of consent material is required, this will be done via the recruiting centre's interpreting service. Details of the interpreter should be recorded in the medical record.

4.3 The use of friends or family members for translation is prohibited.