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Sponsor Standard Operating Procedure

Title: **PARTICIPANT RECRUITMENT AND CONSENT**

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1. v1.0 14th November 2008	1. Clause 4.7 clarification regarding identifiable data leaving the site.

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1. PURPOSE and SCOPE

PURPOSE:
To describe the procedures to be followed and the documentary evidence required for informed consent and participant recruitment into clinical trials.

SCOPE:
Applicable to all clinical trials where informed consent is to be sought from participants.

2. NOTES

2.1 The term 'participant' refers to any individual recruited into a trial. The term includes patients undergoing treatment or trial interventions, or healthy individuals who are given trial interventions or who are recruited for control purposes.

2.2 The exact procedure for participant recruitment should be detailed in the individual study protocol. The study protocol should state clearly the consent process, the planned number of participants and the time period to achieve this. All relevant staff working on studies must be completely familiar with the recruitment and consent procedure.

2.3 The Chief Investigator has overall responsibility for the maintenance of recruitment records as specified in this SOP and in accordance with the study protocol. This may be delegated to authorised personnel at their site and this documented on the Site Responsibility Log, RF2 TA008, as per SOP TA008, Trial Initiation.

2.4 The Principal Investigator (PI) and/or other appropriately qualified and designated staff in each participating trial site must clarify the recruitment strategy for any particular trial. The PI is responsible for the instruction of co-investigators or other Consultants and medical staff working in the same disease area to ensure their awareness of the trial and the eligibility criteria.

2.5 The Principal Investigator has responsibility for the maintenance of recruitment records as specified in this SOP for their site. This may be delegated to authorised personnel and this documented on the Site Responsibility Log, RF2 TA008, as per SOP TA008, Trial Initiation.

2.6 Assent to enter a trial may be given by a legal representative of the potential participant in accordance with Statutory Instruments 2004, 1031 and 2006, 2984 and their amendments and/or in accordance with the Mental Capacity Act, 2005.

3. CROSS REFERENCES

3.1	Trial Initiation	SOP TA008
3.2	Site Responsibility (Delegation) Log	RF2 TA008
3.3	Trial Master File, Trial Site File: set-up and Maintenance	SOP TA010
3.4	Participant Screening and Enrolment Log	RF1 TA011

4. PROCEDURE

4.1 Every person who is considered a potential candidate for the trial should be recorded on the Participant Screening and Enrolment Log, RF1 TA011 regardless of how likely they are to give their consent, or whether there might be other reasons that will prevent the person enrolling into the trial.

4.2 The Principal Investigator, Co-investigator or other delegated personnel such as a Research Nurse will discuss the study with the potential participant and obtain their or their legal representative's informed consent according to the procedure in the study protocol.

Pre-Trial Testing

4.3 In some studies, initial screening tests pertinent to the study will have been done before informed consent for study entry is obtained. Reference must be made to the protocol for specific details. However written informed consent will be required from participants prior to any invasive test needed only for screening purposes of the trial. It is important that participants are aware that they are consenting for tests to discern their eligibility for a particular trial and dependant on the results may or may not be eligible to enrol onto the trial.

Trial Enrolment

4.4 Once identified, eligibility established and consent obtained the participant is enrolled onto the trial following the procedure as outlined in the study protocol and allocated a unique study number.

Note: The allocation of a unique study number means that there must be no duplication of study number regardless of the number of participating sites i.e. there should only ever be one participant with the study number 001 and 002 and so on, in the trial as a whole.

4.5 The date of the enrolment (accrual to the study) of a participant will be the day that consent has been obtained. Enter this date on RF1 TA011, Participant Screening and Enrolment Log. The allocation of the unique study number and any trial related interventions must follow or be concurrent with this date.

4.6 For multi-site trials each participating site shall keep its own Participant Screening and Enrolment Log. The entries must be in chronological order but of course will not necessarily be consecutive (see note above).

4.7 The Chief Investigator shall keep a master list of all trial participants. This may be generated from the trial database or as a master Participant Screening and Enrolment Log which lists all participants recruited at all participating sites. No identifiable information of those approached but not consented to the trial must leave the participating site.

Records

4.8 Store RF1 TA011, Participant Screening and Enrolment Log in the Site File for the trial. The Chief Investigator shall store the master Participant Screening and Enrolment Log in the Trial Master File.

4.9 Update the trial database and the Sponsor Research Database as necessary with the accrual figures.