STATEMENT

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1. **BACKGROUND**

A requirement of International Conference Harmonisation (ICH) Good Clinical Practice (GCP) (section 4.1) is to select research investigators and research sites that are able to assume responsibility for the proper conduct of the study. The investigator should have appropriate experience in the area, have resources to carry out the study and experienced staff to whom they can delegate significant research related duties. In addition, the site has to be able to demonstrate the potential for recruiting the requirement number of suitable subjects within the agreed recruitment period.

Sites must also be initiated before recruitment begins. This involves investigators and site staff being trained in the protocol, in use of any equipment to be used, any other study specific procedures and data collection tools required.

2. **PURPOSE**

To describe the responsibilities for site recruitment and initiation, taking into account Sponsor requirements. Detailed guidance for carrying out site feasibility to inform site selection can be found in the Newcastle Clinical Trials Unit (NCTU) Site Feasibility Working Instruction (WI) and for site initiation in the NCTU Site Initiation and Training WI.

3. **SCOPE**

This Standard Operating Procedure (SOP) applies to all Trial Management personnel within NCTU when conducting site initiation procedures on behalf of the research sponsor.

4. **ROLES & RESPONSIBILITIES**

The Sponsor is responsible for selecting appropriate Investigator(s) and Institution(s) for a particular study, although in non-commercial studies this task is often delegated to the Chief Investigator (CI). This involves checking that the study is feasible at site and the site can support the delivery of the study.

The Sponsor is responsible for site initiation, although in non-commercial trials this is often delegated to the CI or authorised member of the research study team. For Clinical Trials of Investigational Medicinal Products (CTIMPs) that fall within the scope of the European Clinical Trials Directive 2001/20/EC, the Sponsor has a legal obligation for securing arrangements to initiate the trial.

Prior to initiating a trial, the Sponsor must define, establish and allocate all trial-related duties and functions. This is done via a delegation of duties document or service level agreement between NCTU and Sponsor and via the individual agreements between each site and sponsor for site related duties and functions.
5. **ACRONYMS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CI</td>
<td>Chief Investigator</td>
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<tr>
<td>CRF</td>
<td>Case Report Form</td>
</tr>
<tr>
<td>CTIMP</td>
<td>Clinical Trial of an Investigational Medicinal Product</td>
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<tr>
<td>CV</td>
<td>Curriculum Vitae</td>
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<td>GCP</td>
<td>Good Clinical Practice</td>
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<td>HRA</td>
<td>Health Research Authority</td>
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<td>ICH</td>
<td>International Conference on Harmonisation</td>
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<tr>
<td>IMP</td>
<td>Investigational Medicinal Product</td>
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<tr>
<td>ISF</td>
<td>Investigator Site File</td>
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<tr>
<td>LCRN</td>
<td>Local Clinical Research Network</td>
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<td>NCTU</td>
<td>Newcastle Clinical Trials Unit</td>
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<td>PI</td>
<td>Principal Investigator</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>SIV</td>
<td>Site Initiation Visit</td>
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<tr>
<td>TMF</td>
<td>Trial Master File</td>
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<tr>
<td>WI</td>
<td>Working Instruction</td>
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6. **PROCEDURE**

6.1 **Responsibility for site selection**

Careful site selection ensures that study resources are directed towards well motivated, qualified staff, with the potential to recruit eligible participants, generate high quality study data and conduct the study within the context of relevant regulations or guidelines.

Each Investigator must be qualified by education, training and experience and must have adequate resources to properly conduct the study. Qualifications must be documented and provided to the Sponsor as evidence of an Investigator’s suitability. This must be in the form of current Curriculum Vitae (CV) including evidence of GCP training, or other documentation.

6.2 **Site selection**

Potential Investigator(s) and institution(s) are assessed by the CI and trial team to confirm their suitability. This assessment should include a review of the site’s:

- Interest and willingness to participate
- Qualifications and training requirements of site staff
- Potential to recruit eligible participants
- Facilities/equipment/resources to conduct the study appropriately

Potential Investigators must consider their interest in the study, their ability to conduct the study in accordance with relevant regulations/guidelines and confirm their willingness to enter eligible participants. Investigators have a responsibility under the GCP guidelines (section 4.2.1) to meet the recruitment target agreed to with the study sponsor.
Details of any pre-initiation site selection and feasibility contact to assess site suitability (e.g. site visit, telephone calls) must be documented and any issues raised must be followed up promptly. This should be in the form of the NCTU feasibility template document, completed by the Trial Manager. If a site visit is required to discuss the above, this should be documented in the form of a written pre-study report prepared by the Trial Manager, reviewed by the Senior Trial Manager and reported to the Sponsor by the Trial Manager.

For non-commercial studies, a pre-study visit may be deemed unnecessary, particularly if site staff and facilities are already known to the Sponsor or CI.

Under the Health Research Authority (HRA) processes all sites must assess their capacity and capability to carry out the study. Following HRA approval written confirmation of capacity and capability (by letter or email) from the site must be in place before the site can open to recruitment.

6.3 Site initiation

Site initiation must be completed prior to recruitment and prior to any trial procedures that require informed consent. A site may be deemed initiated once:

- All essential documents and approvals are in place according to Sponsor requirements. This includes any local approvals, study contracts and protocol agreement.
- Investigator(s) are familiar with study requirements, relevant regulations/frameworks and roles/responsibilities.
- The site has been provided with relevant documentation, equipment and/or training to enable site staff to begin trial conduct and recruitment.
- Randomisation system is in place, if applicable.
- For CTIMPs, the study drug is available to the site and adequately stored. Study drug must not be available to a particular site until approvals are in place for that site and the site has undergone a documented green light process.

6.4 Site initiation visits

Site Initiation Visits (SIVs) are a monitoring activity and required prior to recruitment and any trial procedures that require participant informed consent. The nature of the SIV will be determined by the study risk assessment and further information is included in NCTU SOP TM-004 Monitoring a Research Study. Where a visit to a study site is deemed necessary to complete the initiation process, the Trial Manager should follow the guidance provided in the NCTU Site Initiation WI.

6.4.1 Before the initiation visit

The Trial Manager will organise a date for the initiation visit and make sure that key members of the site team are available. Depending on the size of the study and number of sites the CI or delegate(s) may also attend. The site team should include wherever possible: Principal Investigator (PI), co-investigators, local co-ordinators, nursing staff and any others involved in the study e.g. surgeons, radiologists, pharmacists, laboratory staff, data managers, representatives from the Local Clinical
Research Network (LCRN). A specific visit to pharmacy or local laboratories may need to be incorporated to review specific Investigational Medicinal Product (IMP) or sample requirements.

The Trial Manager, CI and/or delegate will prepare the SIV slides (version controlled) prior to the initiation visit. Guidance on recommended content is included in NCTU Site Initiation WI and all documentation must be version controlled in accordance with NCTU SOP GE-003 Document Control. The Trial Manager should provide a copy of the slides to the site team prior to the initiation meeting.

The Trial Manager should confirm all relevant details of the forthcoming initiation visit in writing. The site should retain the original correspondence within the Investigator Site File (ISF) and the Trial Manager should ensure a copy is filed in the Trial Master File (TMF).

6.4.2. Study documentation and supplies

ISF, Case Report Forms (CRFs) and all other study documentation and supplies should be on site when the site initiation visit is conducted. If not, the Trial Manager should discuss the date they will be sent to the site at the visit.

Attendance at the SIV must be clearly documented through a completed initiation visit attendance sheet that has been signed by all present. The Trial Manager must ensure the original is filed in the TMF.

6.4.3. Following the initiation visit

Details of site initiations must be documented and the Trial Manager should complete the NCTU Site Initiation Report template to include the visit date, site, name of persons in attendance, summary of any issues discussed and outstanding queries. The completed initiation report must be reviewed by the Senior Trial Manager and finalised within 21 days of the initiation. A copy of the report should be provided to the CI and Sponsor. The original signed report should be held in the TMF, along with a copy of the initiation slides, site follow-up letter and attendance details. Any issues raised must be followed up promptly with the site and prior to the site being deemed initiated. Once issues are resolved the Trial Manager should issue the site with a written statement to confirm this and also issue a green light checklist to be signed off by the site. Once returned the site can commence recruitment.

7. REVIEW AND MONITORING OF THIS DOCUMENT

This SOP will be reviewed every three years unless there is a change to the applicable legislation or significant revision to the process contained in the SOP.

The use of this SOP will be monitored by the Senior Trial Manager during review of the SIV reports. Compliance with this SOP will also be assessed during the NCTU internal audit schedule.
8. ASSOCIATED DOCUMENTS

- NCTU SOP GE-003 Document Control
- NCTU SOP TM-004 Monitoring a Research Study
- NCTU Site Feasibility Working Instruction
- NCTU Site Initiation and Training Working Instruction
- NCTU Site Initiation Visit Guideline
- NCTU Site Initiation Report Template
- NCTU Site Initiation Visit Attendance Log Template