1. **Scope**

1.1 This SOP applies to Chief Investigators (CIs) of any Clinical Trial of an Investigational Medicinal Product (CTIMP) or Medical Device Clinical Investigation, which is sponsored by the University of Aberdeen (UoA) and/or NHS Grampian (NHSG).

1.2 This SOP describes the procedure for managing a change in CI of a CTIMP or Medical Device Clinical Investigation which may arise due to retirement, resignation, a change in CIs employing institution or inability or other reason to discontinue in their role.

2. **Responsibilities**

Chief Investigator (CI)  
Notify Sponsor as soon as possible of a change to their role as CI.

Sponsor  
Approve incoming CI and seek approval of any relevant third parties.

3. **Procedure**

**Notification and Sponsor approval of a change in CI**

3.1 ▶️ Once it has been formally confirmed that the CI will be leaving/demitting their role, the CI must notify one of the following: Research and Innovation (for the UoA), NHS R&D (for NHSG), the Research Governance Manager (RGM) or the Quality Assurance Manager (QAM). These notifications are in addition to the usual Human Resources unit procedures also required when changing employer or retiring. This notification is also required from CIs of CTIMPs and Medical Device Clinical Investigations which have ended and where trial data is maintained in archived storage.

3.2 The University Business Development Officer (BDO) or NHS R&D Non-Commercial Manager and RGM and/or QAM, as required, shall liaise with the relevant senior staff for approval of the proposed change.
replacement CI for the Trial. The RGM shall also pass the proposed change to the Clinical Studies Oversight Group (CSOG) for approval.

3.3 📘 The BDO or Non-Commercial Manager shall seek and confirm approval from any relevant third parties e.g. funding bodies for the replacement CI.

**Applying for approvals of a new CI**

3.4 ⚠ Once the new CI has been approved by Sponsor/Co-sponsor a substantial amendment must be submitted to the Research Ethics Committee (REC) and the Medicines and Healthcare products Regulatory Agency (MHRA) (see SOP-QA-19 –Amendments).

3.5 📘 The delegation log (TMP-QA-13) and all other study information, including notification to sites for multi-centre trials, must be updated, where relevant, with details of the new CI.

3.6 ⚠ The new CI cannot assume any CI duties for the Trial until MHRA approval, REC favourable opinion and NHS R&D Management Permission has been received.

**Handover to a new CI**

3.7 📘 The outgoing CI must ensure the incoming CI receives a comprehensive handover of all documentation and information relating to the trial including, but not limited to:

- Trial Master File (TMF)
- Investigator Site File, if relevant
- All relevant email communication
- Access to all source documentation

3.8 📘 In the event the trial has ended when the CI leaves the employing institution, the Sponsor shall take responsibility for archived data and any remaining samples until their scheduled destruction. The CI shall ensure arrangements are in place for the Sponsor/Co-sponsors to have access to the trial archived data and samples.

4. **Abbreviations and definitions**

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<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>BDO</td>
<td>Business Development Officer (UoA)</td>
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<td>CI</td>
<td>Chief Investigator</td>
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<td>CSOG</td>
<td>Clinical Studies Oversight Group</td>
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<tr>
<td>CTIMP</td>
<td>Clinical Trial of an Investigational Medicinal Product</td>
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<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
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<td>Research Governance Manager</td>
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<td>TMF</td>
<td>Trial Master File</td>
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5. **Related documentation and references**

- SOP-QA-19 Amendments
- TMP-QA-13 Delegation log

Uncontrolled when printed. Please ensure that you are working on the most up to date version of this SOP.

**Key to symbols** 📘 = Important point to note ⚠ = Warning