SOP-QA-24 V4

Title: Managing a change of CI in a CTIMP or MDCI

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Author: Juliette Snow, Senior Research Development Executive	
QA Approval: Richard Cowie, QA Manager	
Approver: Prof Maggie Cruickshank, R&D Director	
Approver: Prof Siladitya Bhattacharya, Head of School	

GRAMPIAN CLINICAL RESEARCH OFFICE

NHS Grampian

1495 UNIVERSITY OF ABERDEEN

Document History

Version	Description of update	Date Effective
3	Title and Scope updated Abbreviations added at 4	1-8-20
4	Change in job title from Business Development Officer to Research Development Executive throughout. Minor changes to working within section 3.1	9-8-23

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 (MDCI), 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 MDCI 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 Following formal confirmation that a 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 MDCIs which have ended and where trial data is maintained in archived storage.

3.2 The University Research Development Executive (RDE) 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 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 RDE or Non-Commercial Manager shall seek and confirm approval from any relevant third parties eg 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 site 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

CI	Chief Investigator
CSOG	Clinical Studies Oversight Group
CTIMP	Clinical Trial of an Investigational Medicinal Product
MDCI	Medical Device Clinical Investigation
MHRA	Medicines and Healthcare products Regulatory Agency
QAM	Quality Assurance Manager
R&D	Research and Development
REC	Research Ethics Committee
RDE	Research Development Executive (UoA)
RGM	Research Governance Manager
TMF	Trial Master File

5. Related documentation and references

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