R&D Department

Procedure for Auditing Research Conducted at HEYHT

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1. PURPOSE AND WHO SHOULD USE THIS SOP

This standard operating procedure (SOP) outlines the procedure for auditing research conducted at HEYHT.

The procedure described in this document provides HEYHT with a framework for:

- Selecting studies for audit
- Conducting the audits
- Reporting audit findings
- Ensuring HEYHT can fulfil its statutory requirements under the UK Clinical Trials Regulations
- Ensuring HEYHT can fulfil its requirements under the Research Governance Framework for Health and Social Care 2005 (2nd Edition)
- Ensuring corrective and preventative actions are put in place as necessary and that appropriate escalation of unresolved issues occurs.

2. INTRODUCTION/BACKGROUND

2.1 Audit Requirement

The purpose of the audit of research activity is to evaluate trial conduct and compliance with the approved trial protocol, SOPs, GCP and regulatory requirements. The audit process should facilitate increased awareness of HEYHT policies as well as demonstrating robust research systems and processes that ensure participant and staff safety. In turn the process should also help to yield increased data quality.

The audit process should be independent of separate routine monitoring but form a part of implementing quality assurance and ongoing review for continuous improvements.

2.2 Responsibilities of HEYHT as sponsor

The Research Governance Framework stipulates that the sponsor is responsible for the management and monitoring of a study.

Monitoring is an integral role in the Quality Control (QC) of a clinical trial and is designed to verify the quality of the study. Audits are designed to assess and assure the reliability and integrity of a trial’s quality control systems and are a way of measuring performance against recognised standards (Quality Assurance or QA).

Monitoring shall be undertaken on behalf of the Trust (where HEYHT is sponsor) by the R&D Clinical Trials Monitor as per R&D GCP SOP 01. This audit SOP is designed to complement, and not replace, the Trust SOP on monitoring.

Audit shall be undertaken, as outlined in this SOP, by a member of the HEYHT R&D Office staff. The Trust will need to ensure that all staff
undertaking the audits on its behalf are suitably qualified by training or experience. To this end, the auditor shall be responsible for:

- Collecting evidence to enable comparison of current practice with the requirements of research governance, GCP and, where applicable, UK Clinical Trials Regulations.
- Writing a final report detailing all required preventative and corrective actions to be taken (where necessary).

Progress reports submitted to the regulatory authorities and to HEYHT R&D Office will not be seen as constituting or replacing the need for auditing and (for HEYHT sponsored CTIMPs) monitoring. Such progress reports may, however, be used by the auditor to aid study selection.

3. PROCEDURE

3.1 Selecting research to be audited

All HEYHT research activity will be eligible for audit under this SOP.

Studies will be selected based on graded assessment of the following criteria:

- Study Sponsor – (HEYHT, Other non-commercial sponsor (hosted), Commercial).
- Study type - (IMP, non-IMP, device studies, tissue studies, qualitative research).
- Anticipated recruitment levels
- Other identified risks – (as per risk assessment form).
- Any suspected areas of non-compliance brought to the attention of the Trust.

3.2 Audit schedules/plan

An audit plan will be developed by the R&D allocated auditor in advance of the audit taking place. An overall audit plan, encompassing the broad remit and objectives each year, will be registered with the Clinical Audit & Effectiveness Department using CG1 form.

The auditor will make contact with the identified Chief/Principal Investigator in advance of the audit to agree and confirm the date, time and location of the audit as well as the staff members required to be present and any specific areas to be focussed on.

As with any audit process, it is imperative that researchers undertaking work at HEYHT are familiar with the standards on which they will be audited. The audit plan overview (CG1 form) and audit tool will be disseminated to all research teams with enough time being given between this process and the first audit.

The frequency and number of audits to be undertaken will be determined by the volume and type of research being conducted and will be reviewed on an annual basis.

3.3 Audit Tool

The Audit Tool for Research Conducted at HEYHT (Version 1, 02/11/09) will be used for all audits falling under the remit of this SOP. The audit tool will
be reviewed and updated as necessary in accordance with regulatory and other procedural changes.

A multitude of audit techniques will be at the auditor’s disposal to aid the completion of the audit tool including (list not exhaustive); document, study record and reports review; first hand observations, data analysis and face-to-face discussions with key staff.

3.4 Audit Report
An audit report will be completed by the designated auditor and will be fed back to the research team in a timely manner.

The report will include:
- The detailed audit plan/objectives and methodology
- A review of the evidence collected
- A discussion of any conclusions drawn from the audit
- A list of identified gaps in compliance
- An assessment of how well regulatory requirements have been met
- Recommendations for change in practice to conform to regulation
- A date for recommended review

3.5 Classification of Audit Findings
Audit findings will be classified using the following criteria:

**Critical:** a finding defined as one with the capacity to directly undermine the integrity of the entire study. For example findings:

- Where evidence exists that the safety, wellbeing, rights or confidentiality of study subjects has been (or has had significant potential to be) jeopardised.

- Where reason has been found to cast serious doubt upon the accuracy and/or credibility of study data.

- Where approval for the study has not been sought from one or more regulatory agency/body or granted from one or more regulatory agency/body (e.g. Ethics committee, MHRA) but the study has commenced regardless.

- Where procedures not covered/included on the consent form are being performed or where new procedures have been introduced into the study protocol but where participants who had consented prior to their introduction have not been asked to re-consent.

- Where following study approval, significant amendments have been made to the study protocol or documentation but no new request for approval has been submitted.

**Major:** A finding defined as one that compromises the integrity of a certain component(s) of the study, for example:

- Where there has been failure to comply with the regulatory requirements e.g. failure to assess and report SAEs and/or SUSARs accurately and to the correct bodies.
• Where there has been a significant unjustified departure from GCP e.g. failure to provide participants with a copy of their consent form or Participant Information Sheet.

**Minor:** Any other audit findings, defined as those where the integrity of the study is not directly compromised but which represent an absence of due diligence on behalf of study staff towards the conduct of the study. For example findings:

• Which demonstrate that no definite document management/organisation processes are in place at site / no investigator site file exists.

• Where there has been failure by study staff to inform the relevant authorities of amendments to start and stop dates or study specific documents.

### 3.6 Follow-up actions and escalation process

Where there are one or more ‘critical findings’ or multiple ‘major findings’, a meeting will be arranged with the research team to ensure appropriate corrective and preventative actions can be put in place to minimise risk to patients and the scientific value of the research. The classification, number of findings in each category and the inability of the researchers to demonstrate improvement plans will determine the escalation of the issues highlighted in the audit.

Critical findings will be automatically presented to the Director of R&D and R&D Manager for review and assessment of the appropriate steps to be taken on a case-by-case basis.

It is the Chief/Principal Investigator’s responsibility to ensure action is taken to correct any identified gaps in regulation compliance. The auditor, in conjunction with the Chief/Principal Investigator, will agree timescales for completion of any actions. Progress reports on any agreed action plans will be requested periodically by the HEYHT R&D Office. Evidence of continued non-compliance or failure to address the audit findings will be passed to the Director of R&D for resolution.

### 3.7 Independent Audit from partner Trust(s)

As part of the ongoing quality assurance and improvement review at HEYHT R&D Office, the Director of R&D will – as is deemed necessary – call upon a partner hospital Trust (from within the local Strategic Health Authority) to undertake an independent audit of research activity, systems and processes.

This independent audit process will be agreed as part of a reciprocal programme of audit between Trusts and will be invoked in random cases and where there are suspected or actual issues warranting an independent review.

### 4. IMPLEMENTATION

Implementation of this SOP will conform to the process outlined in RD SOP01 Production of SOPs.
5. RELATED SOPs and FORMS

Audit Tool for Research Conducted at HEYHT v1, 02/11/09

R&D GCP SOP01

6. REFERENCES


UK Clinical Trials Regulations

ICH GCP Guidelines 1996.

7. ACKNOWLEDGEMENT

This SOP has been adapted, with kind permission, from Imperial College London, CRO/SOP/018: Clinical Research Governance Office Audit SOP.