

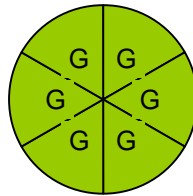
Internal Audit



Research & Development

September 2016

Report Assessment



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Introduction

NHS Lothian has an international reputation for clinical research, which it carries out in conjunction with several universities, commercial pharmaceutical companies and other organisations as a partner. It supports around a thousand projects every year by providing advice and support via the Academic and Clinical Central Office for Research and Development (ACCORD), in partnership with the University of Edinburgh.

Research carried out by NHS Lothian staff has contributed to changes in clinical practice and informed international guidelines, improved outcomes for many patients worldwide, and generated substantial savings across the NHS. As such, in order to continue realising these benefits research activity must be adequately monitored and assessed, and funding streams protected by complying with the conditions of funding received.

Scope

In accordance with the 2015/16 Internal Audit plan we performed a review of the Board's arrangements for the management of Research and Development activity.

This review assessed the controls in place to provide assurance that costs of research and development undertaken by NHS Lothian are covered by funding received, and that projects are subject to appropriate scrutiny.

Acknowledgements

We would like to thank all staff consulted during this review for their assistance and cooperation.

Executive Summary

Conclusion

There are appropriate controls in place to manage Research & Development (R&D) work within the organisation, which include the effective scrutiny and approval of research projects, the creation of legal agreements which include dispute resolution clauses, and effective monitoring of projects to confirm that they are adhering to their terms and conditions of funding. However, three minor control issues were noted, which if addressed would further strengthen arrangements.

Summary of Findings

The table below summarises our assessment of the adequacy and effectiveness of the controls in place to meet each of the objectives agreed for this audit. Definitions of the ratings applied to each action are set out in Appendix 1.

No.	Control Objective	Control objective assessment	Number of actions by action rating			
			Critical	Significant	Important	Minor
1	NHS Lothian has procedures in place which ensure that proposed research activity is fully evaluated in terms of cost/benefit and achievability.	Green				2
2	NHS Lothian has procedures in place which ensure that funding applications are made to appropriate bodies, are sufficient to meet the costs of research, and are scrutinised and approved at an appropriate level.	Green				
3	There is a policy, or agreement is obtained from partner organisations, which ensures that the NHS Lothian retains entitlement to an appropriate share of revenue generated by Research and Development outcomes.	Green				
4	NHS Lothian has procedures in place which ensure that research activity is effectively managed and complies with terms and conditions of funding.	Green				

No.	Control Objective	Control objective assessment	Number of actions by action rating			
			Critical	Significant	Important	Minor
5	There is regular reporting on the impact of Research and Development activity.	Green				
6	Arrangements are in place to manage the risk exposure to NHS Lothian regarding Research Activity.	Green				1

Control Objective Ratings

Action Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention (60 points and above)
Amber	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points)
Green	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less)

Main findings

The R&D department has procedures in place to provide guidance on the scrutiny and approval of potential R&D projects. In addition, there is oversight of key trials by the external organisation the Medicine & Healthcare Products Regulatory Agency (MHRA).

Legal agreements for projects are based on templates which have been approved by the Central Legal Office (CLO). All contracts contain dispute resolution clauses, and the CLO will represent NHS Lothian as required in any disputes.

The R&D team maintains records for projects which note when they are expected to start and when they are expected to end. The R&D team will review higher-risk projects, e.g. those involving human trials and those of significant complexity, at pre-determined intervals or milestones to confirm that they are adhering to their terms and conditions of funding, and are maintaining safety standards.

Each year the R&D team provides a report to NHS Lothian's Board which sets out the key R&D work performed and its benefits to patients and the organisation. In addition, R&D has a strategy for the period 2016-20 which will be provided to the Board in October 2016.

We identified two minor issues for improvement during the review.

- of the 22 projects sampled by the audit, 2 (9%) did not have an IRAS form, which provides details of the project and includes sign-off by the project lead. In addition, for the 22 projects sampled, for 4 (18%) the R&D team did not hold copies of the approvals from the departments involved. Finally, of the 22 projects sampled, costing documentation was not held by the R&D team for 3 (14%) of them; and
- although risk assessments performed by the R&D team are detailed and include statements on project risks, the likelihood of the risk occurring, and actions to mitigate risk, there is no statement on the likely impact of any risks.

Further details of these points are set out in the Management Action Plan.

Management Action Plan

Control objective 1: NHS Lothian has procedures in place which ensure that proposed research activity is fully evaluated in terms of cost/benefit and achievability.

1.1: Not all project documentation is in place

Minor

Observation and Risk:

The Integrated Research Application System (IRAS) is an online system for preparing applications for health and social care research. The form includes detailed information about projects and has sign-off by the project lead. All projects submitted to NHS Lothian's R&D team for approval must have an accompanying IRAS form.

However, of the 22 projects sampled by the audit, 2 (9%) (2007/W/G/04 and 2008/R/RM/06) did not have an IRAS form as part of the project documentation held within the R&D department. R&D staff stated that paper copies of these documents, which were for projects started in 2007 and 2008 respectively, would be in off-site storage.

All research projects within NHS Lothian must have prior approval from the departments where the research is to be conducted. However, for the 22 projects sampled, for 4 (18%) the R&D team did not hold copies of the approvals from the departments concerned. For 3 of these (2013/0110C, 2008/R/RM/06, and 2007/W/G/04) the R&D team stated that there were paper copies of the documents held in off-site storage, while the documentation for the remaining project (2015/0250C**) had been lost due to an error during the migration to a new electronic system.

For each project, the R&D team will calculate any costs to NHS Lothian. Costs can include the use of consultant time and administrative tasks such as the recruitment of patients. However, of the 22 projects sampled by this review, costing documentation was not held by the R&D team for 3 (14%) of them. Of these 3, 2 were for projects from 2007 and 2008 (2007/W/G/04 and 2008/R/RM/06), and the remaining one was for 2015 (2015/0250C**).

If project documentation is not available for review then there is reduced confidence that the project had been effectively reviewed and approved.

Recommendation:

All relevant documentation for all projects, including costing information, should be electronically stored within R&D systems.

Management Response:

It is acknowledged that during the process of moving from paper files to electronic files in 2013 a very small proportion of documents may not have been scanned and saved electronically (in error) e.g. IRAS forms, sign-offs/e-mails from Heads of Service and finance costings (in support of grants). As discussed with the auditor during the audit, all paper files produced by the ACCORD team for studies that are now completed (e.g. R&D files, Trial Master Files and Sponsor files) are archived off-site (Crown Records Management). This facility that has been audited by our QA team.

There are robust procedures in place to ensure that all the necessary paperwork is available prior to R&D Management Approval sign-off of a study. Our SOP GS001 (Management

Approval) and the associated checklist should ensure that IRAS forms and all necessary approvals (including Heads of Service emails) are in place prior to management approval. These documents are stored electronically on SReDA and on the NHS R&D (S/;) drive.

Management Action:

The missing documents from commercial study 2015/0250C** were stored in an electronic file that has been deleted in error. Steps are being taken to obtain e-mails/documentation for this trial to recreate the electronic file.

All academic grant costings that come through the NHS Lothian R&D finance office are recorded in the Finance Grant Review Register and in the Grant Application Folder. These are retained centrally on the NHS Lothian R&D (S/;) drive.

For commercial studies, costings are held in study specific folders, also held centrally on the NHS Lothian R&D (S/;) drive.

Responsibility:

Commercial Research Contract Coordinator (Study 2015/0250C** action)

Target date: End December 2016

Control objective 2: NHS Lothian has procedures in place which ensure that funding applications are made to appropriate bodies, are sufficient to meet the costs of research, and are scrutinised and approved at an appropriate level.

We identified no significant issues in relation to this control objective.

Although it is the responsibility of project leads to petition funding bodies, the R&D team will provide advice as required. There are R&D department procedures which provide guidance on how to ensure that applications are scrutinised and approved at the appropriate level. In addition, the external organisation the Medicine & Healthcare Products Regulatory Agency (MHRA) will review clinical trials and must approve them before they can commence.

Phase 1 projects (which include first in humans clinical trials) need to be approved by the MHRA, the R&D team, the Research Ethics Committee and in addition by NHS Lothian's Phase I Study Research Committee.

Control objective 3: There is a policy, or agreement is obtained from partner organisations, which ensures that the NHS Lothian retains entitlement to an appropriate share of revenue generated by Research and Development outcomes.

We identified no significant issues in relation to this control objective.

Legal agreements for projects are based on templates which have been approved by the Central Legal Office (CLO), with minor variations included where necessary. No contracts are created for more straightforward studies, e.g. those involving staff questionnaires.

Where a commercial firm pays NHS Lothian to perform project work on its behalf, the project legal agreement will state that the firm will have all intellectual property (IP) rights. For contracts between NHS Lothian and another public body (e.g. the University of Edinburgh), the split of any IP will be determined by discussion at the conclusion of the project.

All contracts contain dispute resolution clauses, and the CLO will represent NHS Lothian as required in any disputes.

Control objective 4: NHS Lothian has procedures in place which ensure that research activity is effectively managed and complies with terms and conditions of funding

We identified no significant issues in relation to this control objective.

The R&D team maintains records for projects which note when they will start and when they are expected to end. The R&D team will review higher-risk projects at pre-determined intervals or milestones to confirm that they are adhering with their terms and conditions of funding, and are maintaining safety standards.

Control objective 5: There is regular reporting on the impact of Research and Development activity.

We identified no significant issues in relation to this control objective.

Each year the R&D team provide a brochure to NHS Lothian's Board which sets out the key R&D work performed and its benefits to patients and the organisation. In addition, R&D has a strategy for the period 2016-20 which will be provided to the Board in October 2016 and which states longer-term objectives and challenges.

In addition to there being a Research & Development Committee, there is also attendance by senior R&D staff at senior NHS Lothian committees to discuss R&D work and answer questions.

Control objective 6: Arrangements are in place to manage the risk exposure to NHS Lothian regarding Research Activity.

6.1: Not all project risk assessments are comprehensive

Minor

Observation and Risk:

Risk assessments are conducted for non-commercial CTIMP (Clinical Trial of an Investigational Medical Product) projects sponsored by NHS Lothian, and for other non-commercial projects which have significant complexities. Risk assessments for commercial projects are performed by the sponsoring firms.

Risks stated in NHS Lothian's Datix electronic system are based on a risk scoring which reflects both the likelihood of the risk occurring and its impact. This process allows risks to be prioritised.

However, although risk assessments performed by the R&D team are detailed and include statements on project risks, the likelihood of the risk occurring, and actions to mitigate risk, there is no statement on the likely impact of any risks.

There is a risk that project risks are not fully understood.

Recommendation:

Project risk assessments should include an assessment of the impact of each risk.

Management Response:

The conduct and documentation of risk assessments of CTIMPs and complex research projects is one of the key processes for sponsors, and for CTIMPs is a regulatory requirement.

Our risk assessment team is multidisciplinary and includes ACCORD staff from Research Governance (NHS Lothian & University of Edinburgh), R&D, Quality Assurance and the Clinical Trial Monitoring team. In addition to ACCORD staff, we also invite expert opinion from Investigators and research teams, pharmacy and other support departments where considered appropriate. The perceived risks are discussed in detail during these meetings and any mitigation documented reflects consideration of the perceived risks and the impact should these occur.

As it is a regulatory requirement, we have worked closely with the MHRA in the development of our Risk Assessment SOP and associated documentation. In fact, the MHRA have used our Risk Assessment tool as an example on their forum website

(<http://forums.mhra.gov.uk/showthread.php?1678-Examples-of-risk-assessments>).

However, we do acknowledge that other examples on this website do include impact assessment, and it is something that we would consider including in our risk assessment tool in future.

Management Action:

The inclusion of impact assessment in the ACCORD Risk Assessment tool will be discussed

at our next Sponsorship Committee meeting, which includes key personnel from NHS Lothian and the University of Edinburgh. If the committee agrees that this change is appropriate, the SOP and associated documentation will be updated to include impact assessment. If the committee don't think this is necessary at this point, the QA manager will note this for future consideration (in the ACCORD QMS) at the next review/update of this document.

Responsibility: QA Manager to raise with Sponsorship Committee

Target date: End October 2016

Appendix 1 - Definition of Ratings

Management Action Ratings

Action Ratings	Definition
Critical	The issue has a material effect upon the wider organisation – 60 points
Significant	The issue is material for the subject under review – 20 points
Important	The issue is relevant for the subject under review – 10 points
Minor	This issue is a housekeeping point for the subject under review – 5 points

Control Objective Ratings

Action Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention (60 points and above)
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