Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

STH Researcher

Independent Scientific Review

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Standard Operating Procedure: STH Researcher

Independent Scientific Review

This SOP has been produced in accordance with DoH Research Governance Framework 2005. This SOP will outline the procedure for the agreement and approval of evidence for scientific review of all research projects undertaken at Sheffield Teaching Hospitals NHS Foundation Trust (STH).

Background

A requisite of the DoH Research Governance Framework is that all proposals for health and social care research must be subjected to review by experts, in the relevant fields, able to offer independent advice on its scientific quality. Furthermore, all research sponsors must have systems in place, or have access to systems to undertake expert independent review, appropriate to the scale and complexity of research proposals, to allow the organisation to satisfy itself on the scientific standing of the work, its strategic relevance and value for money. Before a project is authorised by STH, evidence of satisfactory scientific review must be obtained for each research project.

This SOP applies to STH Sponsored studies:

- Studies without funding or funded from investigator own accounts
- Studies funded by grants, charities or research councils where there is no evidence of ISR
- Student studies (whole or part of a graduate qualification)
- STH Sponsored CTIMPS
- Studies funded from a commercial grant where there is no evidence of ISR

For studies at STH that are externally Sponsored, the investigator forwards the protocol with appropriate regulatory approval and evidence of scientific review to the Research Co-ordinator.

Definition

Peer review or scientific review (hereafter referred to as Independent Scientific Review: ISR) is the assessment of a research proposal by experts ('reviewers') in the relevant fields able to offer independent advice on its scientific validity. Evidence of ISR is defined as the report provided by the experts undertaking the review of the proposal.

1. General Procedure:

1.1. The STH investigator registers their research project with the Research Department. A dedicated R&D Coordinator will be assigned to the study.

1.2. For all STH research projects, the investigator, when writing the protocol, should follow the guidance provided on the current Protocol outline template and Writing a Protocol document, found at http://www.sheffieldclinicalresearch.org/clinical-research-office/useful-documents.

   i. If the study is a STH Sponsored CTIMP the procedure outlined in section 2 of this SOP is followed.
   ii. If the study is being conducted in the STH Clinical Research Facility (CRF) the procedure outlined in section 3 of this SOP is followed.
   iii. If the study is a STH Sponsored Commercial grant study the procedure outlined in section 4 of this SOP is followed.
   iv. All other studies undergo the process described below in this section.

1.3. The investigator will obtain appropriate Directorate Approval for the study (by email, committee approval or Directorate Approval form), and submit this to the Research Department. The Research Governance process will not start until this approval has been received. The dedicated R&D Coordinator can provide relevant advice.

1.4. The investigator submits an electronic copy of the protocol and any supporting documentation (investigator CV, Informed Consent Form, Patient Information Sheet) for STH ISR to the dedicated R&D Coordinator or directly to the ISR Administrator. The dedicated R&D Coordinator requests the names of suggested reviewers[1] from the investigator:

[1] A reviewer will not have or had any input into the design, supervision, recruitment, conduct and subsequent analysis of the study

i. For all non-student studies the names and contact details of a minimum of 3 suggested independent reviewers is requested.
ii. For student studies[2] the name of a minimum of 2 reviewers will be requested from the supervisor or student, these can be from within the department where the project will be conducted.

1.5. The dedicated R&D Coordinator forwards the protocol and supporting documentation for STH ISR to the ISR Administrator.

1.6. The ISR Lead performs a first pass review (FPR) whereby the ISR submission is reviewed against the Protocol outline template.

1.7. Following FPR the ISR Lead sends an e-mail to the ISR Administrator informing of review findings.
i. If the submission is found deficient, the ISR Administrator emails the investigator with the FPR comments requesting revision and re-submission as appropriate.
ii. If the protocol and supporting documentation meet the criteria listed in the Protocol outline template, the ISR Lead informs the ISR Administrator to forward the submission for review to the identified reviewers.

1.8. The ISR Administrator sends a 'STH request for ISR' email to the identified reviewers listing the project and investigator details for the protocol submitted for review. The ISR Administrator includes a return date, a fortnight from the date of request, for completed reviews. Reviewers are requested to indicate whether or not they are able to undertake the review or if they have a conflict of interest[1]. The ISR Administrator forwards with the email the submitted protocol and any supporting documentation, and a reviewers' checklist for completion by the reviewer.

1.9. If a reviewer indicates they are not able to undertake the review, the ISR Lead identifies another reviewer. The ISR Administrator sends an email request to the new reviewer as before. Where the ISR Lead and Administrator are unable to identify a reviewer, the ISR Administrator sends an email request for recommendations for potential reviewers to the investigator, approached reviewers, or Directorate Research Lead as appropriate.

1.10. When the ISR Administrator is in receipt of all reviewers' comments, the Administrator sends the investigator a 'Results of ISR' email noting the outcome of the review with anonymised reviewers' comments attached. The ISR Administrator confirms whether the investigator is able to proceed with the project authorisation process or asked to re-submit the protocol after revision.
1.10.1. Return of a minimum of two sets of reviewer's comments are required for this process.

1.11. If the reviewer(s) have requested changes and re-submission, the investigator addresses the comments made and makes the changes as appropriate. The investigator submits their revised documents to the ISR Administrator or ISR Lead for re-review by the appropriate reviewer.

1.12. If ISR is complete and the reviewers have indicated their approval, the investigator contacts their dedicated R&D Coordinator and continues to proceed with the project authorisation process.

1.13. If any problems arise with respect to the ISR process (disagreements regarding the reviewers comments or reviewer declines to undertake re-review etc) then the ISR Lead will consult with the Research Manager and/or Director of R&D to resolve on a case by case basis.

2. Procedure for STH Sponsored CTIMP Studies

2.1 The investigator ensures that the protocol for STH Sponsored CTIMPs is written using the current Writing a Protocol document with particular focus on guidance with respect to MHRA compliance.

2.2 The investigator submits the protocol and supporting documentation to the dedicated R&D Coordinator or directly to the ISR Administrator.

2.3 The ISR Lead performs a first pass review (FPR) whereby the ISR submission is reviewed against the Protocol outline template.
i. If the submission is found deficient, the ISR Administrator emails the investigator with the FPR comments requesting revision and re-submission as appropriate.
ii. If the protocol and supporting documentation meet the criteria listed in the Protocol outline template, the ISR Lead informs the ISR Administrator to forward the submission for the next step (Risk-Assessment).

2.4 The study undergoes Risk-Assessment by the QA Lead and/or Research Manager (SOP C118).

[2] Where a department can demonstrate a satisfactory independent review has been undertaken eg through a department peer review process, further ISR may not be necessary.

2.5 The Risk-Assessment process may result in a request for protocol amendment/development, in order to fulfil Sponsorship criteria for CTIMPs, until an agreed version, by the QA Lead and Research Manager, is finalised.
2.6 Following Risk-Assessment the finalised STH-sponsored CTIMP submission undergoes ISR by the Clinical Research Facility Scientific Advisory Board (CRF SAB). The CRF SAB ISR process may result in a request for protocol amendment/development until an agreed version is finalised and approved.
2.7 If any problems arise with respect to the ISR process (disagreements regarding the reviewer's comments etc) then the CRF SAB Chair will consult with the Research Manager to resolve on a case by case basis.
2.8 CRF SAB reviewers' comments are forwarded to the ISR Lead, ISR Administrator and Research Manager to acknowledge as a completed satisfactory review.
2.9 The ISR Lead will, if needed, arrange for statistical review by the Statistical Services Unit (SSU) Clinic, following a positive outcome from the risk-analysis and CRF SAB process.
2.10 Following positive CRF SAB ISR and positive statistical review (if applicable) the investigator will be informed that the study can proceed through the project authorisation process via liaison with the ISR Lead and/or Research Manager.

3 Procedure for studies being conducted in the STH Clinical Research Facility (CRF)

3.1 The investigator ensures that the protocol is written using the current Writing a Protocol document.
3.2 The investigator submits the protocol and supporting documentation to the dedicated R&D Coordinator or directly to the ISR Administrator.
3.3 The ISR Lead performs a first pass review (FPR) whereby the ISR submission is reviewed against the Protocol outline template.
   i. If the submission is found deficient, the ISR Administrator emails the investigator with the FPR comments requesting revision and re-submission as appropriate.
   ii. If the protocol and supporting documentation meet the criteria listed in the Protocol outline template, the ISR Lead informs the ISR Administrator to forward the submission for the next step (review by the CRF).
3.4 For studies undertaken in the CRF, whether STH Sponsored CTIMPs or not, the protocol is reviewed by the CRF Scientific Advisory Board (SAB).
3.5 The CRF SAB ISR process may result in a request for protocol amendment/development until an agreed version is finalised and approved.
3.6 If any problems arise with respect to the ISR process (disagreements regarding the reviewer's comments etc) then the CRF SAB Chair will consult with the Research Manager to resolve on a case by case basis.
3.7 CRF SAB reviewers' comments are forwarded to the ISR Lead, ISR Administrator and Research Manager to acknowledge as a completed satisfactory review.
3.8 Following positive CRF SAB ISR and positive statistical review (if applicable) the investigator will be informed that the study can proceed through the project authorisation process via liaison with the ISR Lead and/or Research Manager.

4 Procedure for STH Sponsored Commercial grant studies (non-CTIMP and non-CRF studies)

4.1 The investigator, if writing the protocol for STH Sponsored Commercial grant studies, ensures it is written using the current Writing a Protocol document.
4.2 The investigator submits the protocol and supporting documentation to the dedicated R&D Coordinator or directly to the ISR Administrator. ISR is dependent on:
   i. If this protocol has been reviewed by the commercial funder, the investigator submits the reviewers' comments to the dedicated R&D Coordinator or ISR Lead.
   ii. If the reviewers' comments are not available due to non-release by the commercial body, the R&D Coordinator requests a description of the review procedure of the commercial body from either the investigator or commercial body as appropriate.
   iii. If a review has not been performed then the procedure outlined in section 1 of this SOP is followed.
4.3 The ISR Lead scrutinises the reviewers' comments or the description of the review procedure to confirm whether:

i. The review is satisfactory (the review system is well set up, that procedures for review are in place, and if the award scheme is competitive). The ISR Lead and/or Administrator confirm this with the investigator and dedicated R&D Coordinator.
ii. If the evidence for review or supporting evidence for the award scheme is not satisfactory, the ISR Lead requests that procedure outlined in section 1 of this SOP is followed.

4.4 If the investigator declines STH ISR and STH is sponsor for the project, the R&D Coordinator refers this to the ISR Lead and Research Manager; the Research Department can decline authorisation of the project.

4.5 If any problems arise with respect to the ISR process (disagreements regarding the reviewers comments or reviewer declines to undertake re-review etc) then the ISR Lead will consult with the Research Manager and/or Director of R&D to resolve on a case by case basis.

5. Scientific review of Protocol amendments

If changes are made to the study protocol after scientific review approval or after STH project authorisation, the Research Department requires to be notified of the intended amendments, to enable appropriate governance review and confirmation of continued ISR or STH project authorisation to be given.

An amendment is any deviation from, or change(s) to the study protocol during the life of the study.

STH sponsored studies

5.1 The investigator forwards the proposed protocol amendment to the R&D Coordinator.

5.2 The R&D Coordinator and ISR Lead review the amendment against the current protocol.

i. If changes are administrative (considered non-substantial), re-review is not required
ii. If changes are made to the design, methodology, analysis of the research study (considered substantial), it may be necessary for the protocol to undergo re-review and approval. The R&D Coordinator confirms following discussion with the ISR Lead, whether re-review is necessary. If re-review is required the process is discussed with the ISR Lead and taken forward as appropriate (input from the QA Lead will be requested for STH Sponsored CTIMPs).

5.3 Thereafter, the standard process for amendment authorisation is followed by the R&D Coordinator.

For studies at STH that are **Externally sponsored**

5.4 Re-review of amendments is not required for these studies.

5.5 The standard process for amendment authorisation is followed by the R&D Coordinator.

Appendix 1 - Associated Documents

	Document	Location	Website	Created by
1	Protocol Outline	S:\General\Research Governance\Independent Scientific Review\STH_internal_review\Current_Documents\Current ISR documents\Protocol outline_v5 4.doc	Yes	EW/DP
2	Protocol Guidance notes	S:\General\Research Governance\Independent Scientific Review\STH_internal_review\Current_Documents\Current ISR documents\Protocol guidance notes_v1 5 20nov12.pdf	Yes	EW/DP
3	Reviewers' Checklist	S:\General\Research Governance\Independent Scientific Review\STH_internal_review\Prot_reviews\Reviewers checklist_v4.5.doc	No	EW/DP
4	ISR Email Templates	S:\General\Research Governance\Independent Scientific Review\STH_internal_review\Prot_reviews\Email Templates	No	GK