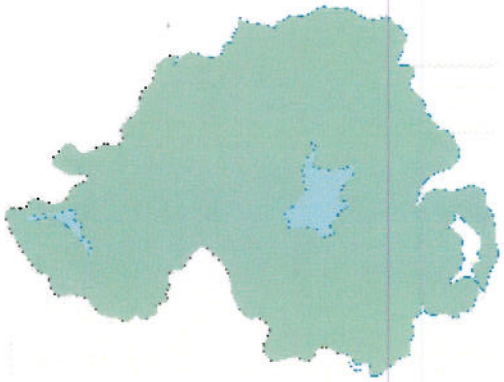
Health and Social Care

HSC Trust Research Governance Permission

Guidance Note 2

Submission of Application

How to Submit the Application for HSC R&D Governance Permission to conduct research in HSC Trusts in Northern Ireland



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Appendices

1 Introduction

1.1 Health and Social Care (HSC) Trust Research Governance Permission has been developed to streamline the process of obtaining research governance permission for research studies involving secondary care in Northern Ireland.

1.2 For single site Studies a standardised permission process is managed separately by each HSC Trust Research Office (Contact details Appendix 1).

1.3 It is recommended that researchers make early contact with the relevant Trust Research Office, before commencing to submit an application for research governance permission. All research applications must be submitted by the Integrated Research Application System (IRAS). Trust Research Offices aim to grant research governance permission within 60 days from receipt of application.

2 Single Centre Study vs Multi-Centre Studies

There are 2 categories of application:

(a) single site studies (involving only one HSC Trust in Northern Ireland), and
(b) multi-centre studies (involving more than one HSC Trust in Northern Ireland)

2.1 Single-site Studies

For single site studies, please make contact with the relevant Trust Research Office (Appendix 1).

Please follow the procedural steps set out in Section 3, alongside the single-centre study flowchart (Appendix 2a) and use of the submission checklist (Appendix 3a).

2.2 Multi-Centre Studies

2.2.1 For multi-centre studies, please make contact with one of the five HSC Trust Research Offices who will identify a lead Trust. The lead Trust role is responsible for completing the global (generic) checks and issuing a global governance report to all participating Trusts. (An internal report for Research Office use only).

Please follow the procedural steps set out in Section 3, alongside the multi-centre study flowchart (Appendix 2b) and use of the submission checklists (Appendix 3b & c).

For multi centre studies being initiated and led from one of the other devolved nation co-ordinating centres (England via CSP, Scotland via NRS Permissions Co-ordinating Centre and Wales via NISCHR Permissions Co-ordinating Unit), the Western Health and Social Care Trust Research Office has agreed to act as the initial point of contact for these applications (Appendix 1).

3 Process of Submitting an IRAS Application

3.1 Once the pre-application stage has been fully completed (see separate Guidance Note 1 on Pre Application for HSC Research Governance Permission) please proceed to submit the IRAS R&D application, together with supporting documents as per checklist (see Appendix 3b), to the Lead Trust Research Office for multi-centre studies. The method of submission should be electronic (preferably word document/pdf), however, hard signed copies may also be submitted by post, if necessary.

3.2 The process of submitting applications for HSC Trust Research Governance Permission for secondary care studies in Northern Ireland is described in the following Procedural steps. It is recommended that these steps are read in association with the flowcharts outlined in Appendix 2.

3.3 Applications to research ethics committees and or other regulatory bodies (e.g. MHRA) may be submitted in parallel of submission to HSC Trust Research Offices.

SINGLE CENTRE STUDY – PROCEDURAL STEPS

STEP	ACTION	RESPONSIBILITY
1	Complete dataset in Integrated Research Application System (IRAS) and collate supporting information and documentation.	**Applicant**
2	Once information is completed, proceed to submit application to the HSC Trust Research Office, as per checklist for single centre study (Appendix 3a)	**Applicant**
3	A valid/invalid application notification is sent to the applicant	HSC Trust Research Office
4	If invalid, revise application or provide additional information as requested and re-submit to the HSC Trust Research Office.	**Applicant**
5	Submit outcome of ethical opinion and any other regulatory approvals, once received, to HSC Trust Research Office. If any submitted documents are revised, re-submit revised documents (version controlled and dated) to HSC Trust Research Office.	**Applicant**
6	Once all global/local checks are complete as part of the final review, the HSC Trust Research Office will issue a letter of full HSC Trust Research Governance Permission or letter of rejection to the CI, with copy to local PI/LC and sponsor.	HSC Trust Research Office
7	Research Project can now commence, once permission is received from the HSC Trust Research Office. Research study becomes active.	**Applicant**
8	If letter of rejection is received, the applicant may appeal in accordance with the arrangements set out by the relevant HSC Trust Research Office, or the applicant may revise and submit a new application.	**Applicant**

MULTI-TRUST STUDY – PROCEDURAL STEPS

STEP	ACTION	RESPONSIBILITY
1	If a Lead Trust has not already been identified, contact one of the Trust Research Offices for guidance on submission. (see Appendix 1)	**Applicant**
2	Complete dataset in Integrated Research Application System (IRAS) and collate supporting information and documentation.	**Applicant**
3	Once information is completed, proceed to submit application to the Lead HSC Trust Research Office, as per checklist for multi-centre studies (Appendix 3b):	**Applicant**
4	A valid/invalid application notification is sent to the applicant.	Lead HSC Trust Research Office
5	If invalid, revise application or provide additional information as requested and re-submit to the Lead HSC Trust Research Office.	**Applicant**
6	Each identified Local Trust contacts the CI and requests the SSI and associated documents, if not already received.	HSC Local Trust Research Office
7	In liaison with the PI/Local Collaborator, submit completed SSI forms and supporting documentation to each participating HSC Trust Research Office (See Appendix 1 for contact details and Checklist for local documentation at Appendix 3c). **It is advisable to seek early advice on completion of SSIs from each HSC Trust Research Office as local requirements may differ.**	**Applicant**
8	Submit outcome of ethical opinion and any other regulatory approvals, once receipted, to Lead HSC Trust Research Office only. If any submitted documents are revised, re-submit revised documents (version controlled and dated) to Lead HSC Trust Research Office.	**Applicant**
9	Once all global checks are complete as part of the final review, the Lead HSC Trust Research Office will produce a Research Governance Report and share with the other participating Trusts (Local).	HSC Lead Trust Research Office

STEP	ACTION	RESPONSIBILITY
10	Once all global/local checks are complete as part of the final review, each HSC Trust Research Office will issue a letter of full HSC Trust Research Governance Permission or letter of rejection to the CI, with copy to PI/Local Collaborator and sponsor.	Lead and Local HSC Trust Research Office
11	Research Project can commence at all approved sites, once permission is received from **each** HSC Trust Research Office. Research study becomes active at approved sites.	**Applicant**
12	If letter of rejection is received, applicant may appeal in accordance with the arrangements for that process within each Trust, or revise and submit a new application.	**Applicant**

4 Receiving HSC Trust Research Governance Permission

4.1 HSC Trust Research Governance Permission remains the responsibility of each HSC Trust Research Office. HSC Trusts are separate organisations and a Lead HSC Trust therefore cannot grant permission for other participating HSC Trusts. It is important to adhere to the conditions set out in the final permissions letter, including the requirement to provide annual reports and notification of study closure to the HSC Trust Research Offices.

5 Amendments

5.1 Permission is granted for the project to proceed on the basis of the protocol and associated documents submitted (with version number and dates) to the HSC Trust Research Office. For a variety of reasons there can be a need to amend research projects and to submit amendments to the National Research Ethics Service (NRES). All amendments, substantial, minor or those deemed by NRES as not requiring ethical approval MUST be submitted with all the supporting documentation to the Trust Research Office and the Sponsor. Some amendments may also be required to be notified to other regulatory bodies, for e.g. MHRA.

Further details on studies requiring amendments can be obtained by contacting the relevant Lead/Local Research Office.

APPENDIX 1

Research & Development Office

Belfast Health & Social Care Trust

Room 2010, 2nd Floor

King Edward Building

Royal Hospitals Site

Grosvenor Road

Belfast, BT12 6BA

Tel: 028 9063 6366

Email:Alison.Murphy@belfasttrust.hscni.net

Research & Development Office

Southern Health and Social Care Trust

Ramone Building

Craigavon Area Hospital

68 Lurgan Road, Portadown

BT63 5QQ

Tel: 028 38614274

Email:Irene.Knox@southerntrust.hscni.net

Research & Development Office

South Eastern Health and Social Care Trust

Room 19, Home 3

Ulster Hospital

Dundonald

Belfast BT16 1RH

Tel: 028 90553101

Email: Paul.Carlin@setrust.hscni.net

Research & Development Office

Northern Health & Social Care Trust

Bush House

Antrim Area Hospital

Antrim BT41 2QB

Tel: 028 94424653/028 27661260

Email: Margaret.Smyth@northerntrust.hscni.net

Research & Development office

Western Health & Social Care Trust

Clinical Translational Research & Innovation Centre (C-TRIC)

Altnagelvin Area Hospital

Glenshane Road

Londonderry, BT47 6SB

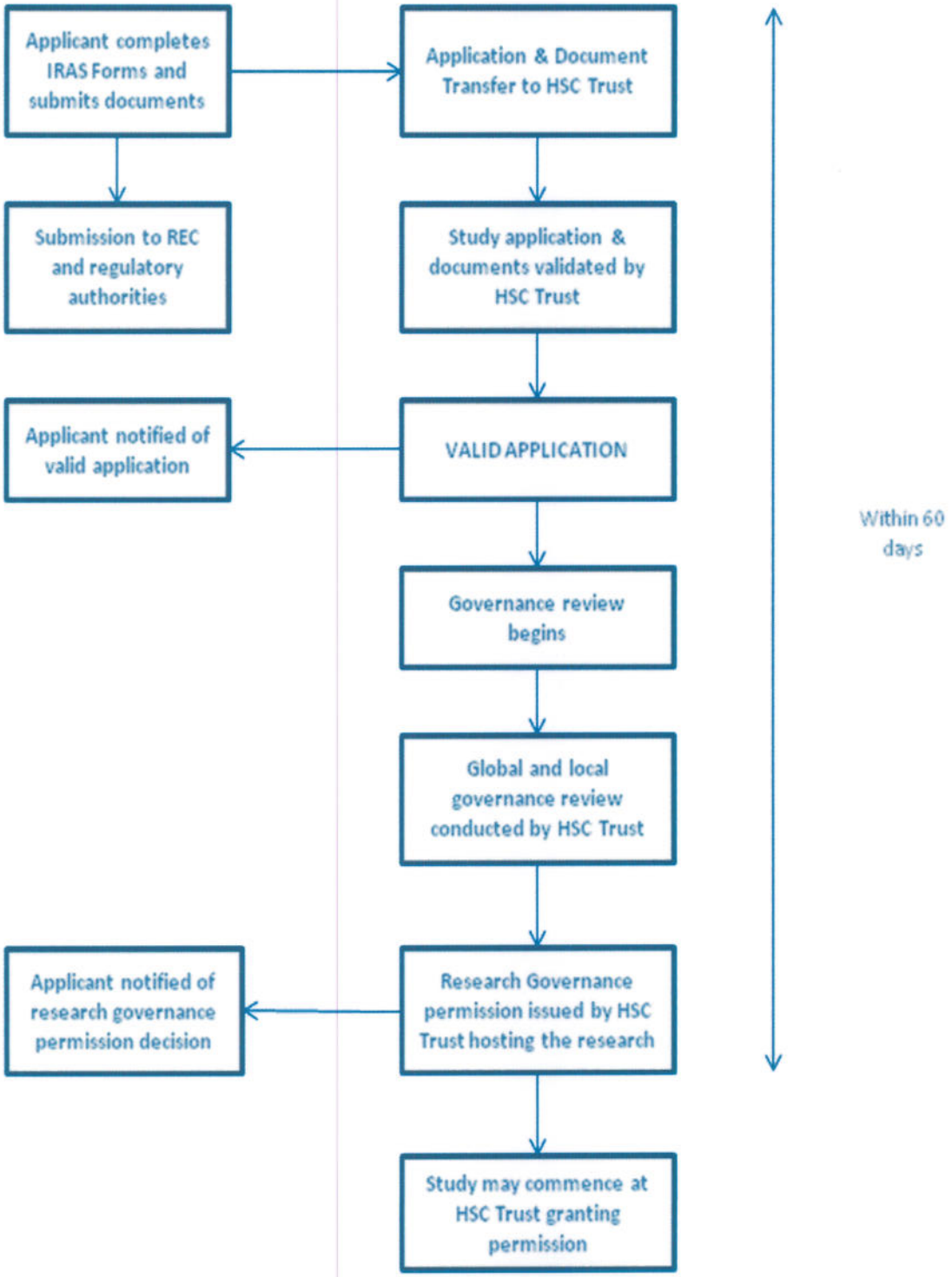
Tel: 028 71611362

Email: Sally.Doherty@westerntrust.hscni.net

APPENDIX 2a

SINGLE HSC TRUST STUDY PROCESS FLOWCHART

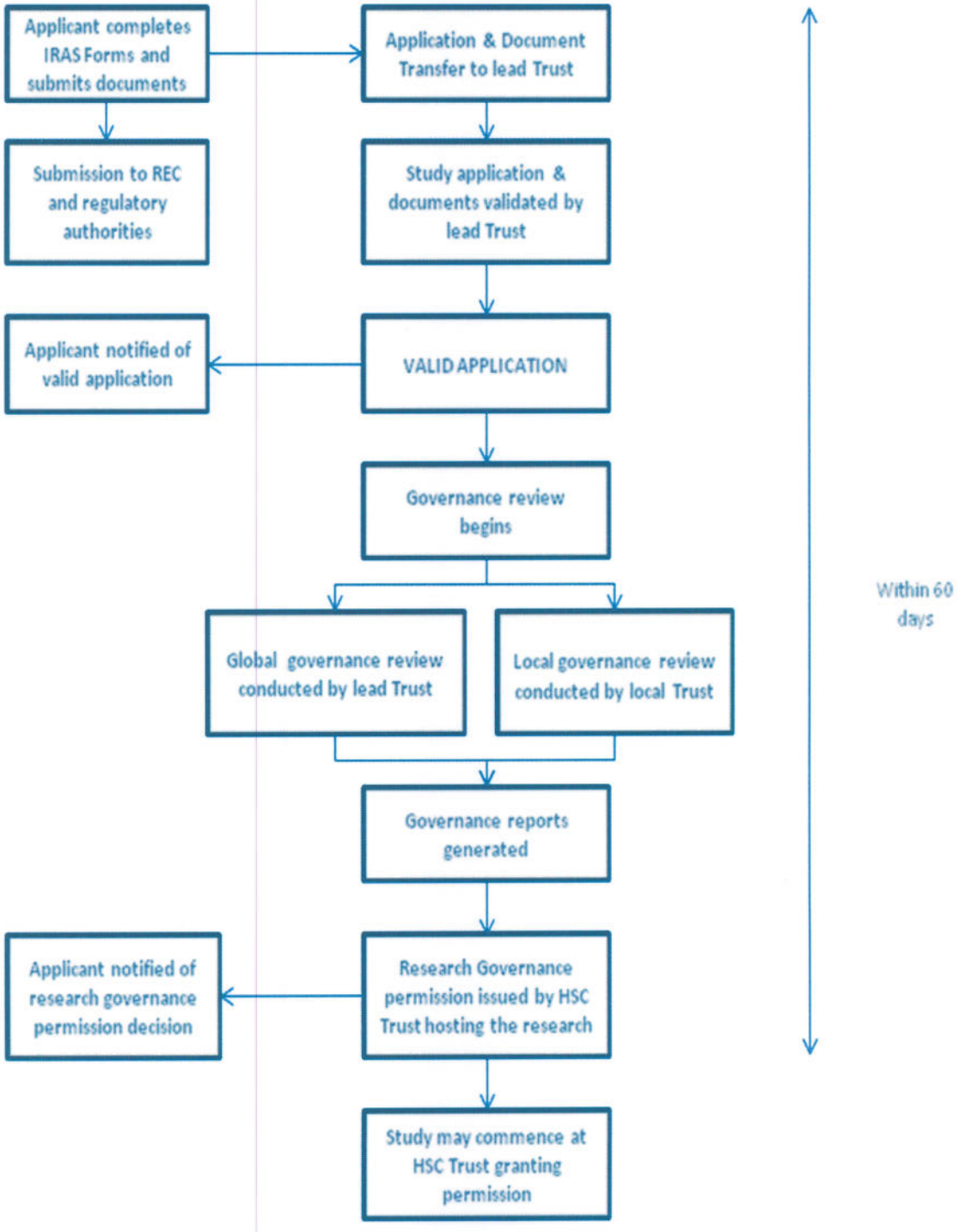
The flowchart for a number of research sites across a single HSC Trust or with a single research site within a single HSC Trust is as follows:



APPENDIX 2b

MULTI HSC TRUST STUDY PROCESS FLOWCHART

The flowchart for research studies with research sites across multiple HSC Trusts is as follows:



Appendix 3a

HSC Trust Research Governance Permission

Single - Centre Project
Document Submission Checklist to HSC Trust

Project Title: _____

Document	Version / Date	Yes	No	N/A
IRAS NHS R&D Form – signed by CI				
IRAS NHS SSI Form – signed by PI				
Protocol				
Participant Information Sheet (PIS)				
Participant Consent Form				
Letters of Invitation*				
GP/Consultant Information Sheets*				
Interview Schedules*				
Sample Diary Card/Patient Card*				
Advertisement Material*				
Validated Questionnaire*				
Non-validated Questionnaire*				
Investigator Brochure/Summary of Product Characteristics*				
Funding Award Letter(s) (non-commercial projects only)				
Confirmation of local funding/costing template*				
Sponsorship Confirmation (Signed IRAS Form acceptable)				
Evidence of insurance or indemnity (Non-NHS Sponsors only)				
Contract/Agreement*				
CV of Chief Investigator				
CVs for local research team				
Evidence of GCP Training for research team				
Local Trust Specific documents*				

Documents required prior to final NHS permission
(may be submitted after the initial application)

Document	Version / Date	Yes	No	N/A
REC (Favourable) Opinion Letter				
MHRA Clinical Trial Authorisation*				
MHRA "Notice of No Objection" Letter (Medical Devices)*				
Gene Therapy Advisory Committee (GTAC) Approval Letter*				
Other Regulatory Approvals*				

*if applicable as per study type

Appendix 3b

HSC Trust Research Governance Permission

Multi - Centre Project
Document Submission Checklist to Lead Trust

Project Title: _____

Document	Version / Date	Yes	No	N/A
IRAS NHS R&D Form – signed by CI				
Protocol				
Participant Information Sheet (PIS)				
Participant Consent Form				
Letters of Invitation*				
GP/Consultant Information Sheets*				
Interview Schedules*				
Sample Diary Card/Patient Card*				
Advertisement Material*				
Validated Questionnaire*				
Non-validated Questionnaire*				
Investigator Brochure/Summary of Product Characteristics*				
Funding Award Letter(s) (non-commercial projects only)				
Sponsorship Confirmation (Signed IRAS Form acceptable)				
Evidence of insurance or indemnity (Non-NHS Sponsors only)				
CV of Chief Investigator				

Documents required prior to final NHS permission
(may be submitted after the initial application)

Document	Version / Date	Yes	No	N/A
REC (Favourable) Opinion Letter				
MHRA Clinical Trial Authorisation*				
MHRA "Notice of No Objection" Letter (Medical Devices)*				
Gene Therapy Advisory Committee (GTAC) Approval Letter*				
Other Regulatory Approvals*				

*if applicable as per study type

Appendix 3c

HSC Trust Research Governance Permission

Multi - Centre Project
Document Submission Checklist to Local Trust

Project Title: _____

Document	Version / Date	Yes	No	N/A
IRAS NHS SSI Form – signed by PI				
CVs for research team				
Evidence of GCP Training for research team				
Confirmation of local funding/costing template (if applicable)				
Contract/Agreement (if applicable)				
Local Trust Specific documents (if applicable)				

Appendix 4

Glossary

Amendment A change made to the terms of an application for NHS permission, the protocol or any other supporting documentation after the study has started. A study is normally considered to start with the commencement of any protocol procedures.

Chief Investigator (CI) The investigator with overall responsibility for the research. In a multi-site study, the CI has coordinating responsibility for research at all sites.

Global governance checks The checks generic to the study. They are undertaken once on be half of all NHS organisations taking part in the study.

Governance checks A number of checks which aim to provide assurances that a study complies with applicable regulatory and statutory requirements.

HSC Health and Social Care

IRAS Integrated Research Application System.

Local Collaborator Studies that do not require a local principal investigator at each site, but require someone that is willing to act as the Trust contact for the co-ordination and facilitation of the research.

Local governance checks The checks required to be undertaken by an individual NHS organisation in respect of the study. They must be conducted by each NHS organisation participating in the study.

MHRA Medicines and Healthcare Products Regulatory Agency.

NHS National Health Service.

NHS organisation All organisations within the National Health Service who provide health or social care (i.e. NHS Trust or Local Health Board).

NHS permission The permission from the NHS organisation providing care to conduct the research at a NHS site before any research procedures are commenced at a particular site, i.e. permission from the Local Health Boards. Also known as R&D approval or Research Governance Approval.

NHS REC Form The application form that collects the study data used by a Research Ethics Committee to review a study. The online form is a smart form designed to save time when completing it. As certain questions are answered, information will auto populate in other relevant places and the answers to certain questions will deactivate or activate other sections of the form.

NHS/HSC R&D Form The NHS/HSC R&D form is split into NHS/HSC R&D form (project information) and NHS/HSC R&D form (SSI). Applications for NHS permission require both forms, the NHS/HSC R&D form (project information) which contains the project-wide information and the relevant NHS/HSC R&D form (SSI) with local information. These forms are used by the R&D or Research Governance offices to review a study. The project-wide information allows the study to be assessed and the SSI local information allows an assessment of the suitability of the local investigator, site and facilities.

NRES National Research Ethics Service.

pdf Portable Document Format.

Principal Investigator (PI) Where the research takes place in more then one site, this is the individual who is responsible for research at a particular site; there will be one PI per site.

R&D Research and Development.

REC Research Ethics Committee.

Research The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.

Sponsor The person who takes responsibility for initiation, management and financing (or arranging finance) for the Research Study

SSI Site Specific Information.

Supporting documentation All documents associated with the main application for obtaining NHS permission.

Validation A check carried out by the HSC Trust Research Office to verify that an application is complete and may be accepted for review.