Health and Social Care

HSC Trust Research Management Permission

(Guidance for Applicants)

How to Prepare and Submit an Application for Health and Social Care Research Studies to HSC Trusts, Northern Ireland

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Appendices

1 Introduction

1.1 In accordance with the UK Policy Framework for Health & Social Care Research (2017), Research Governance Permission is required before a research study can commence in Health and Social Care Trusts (HSC) in Northern Ireland.

1.2 The HSC Trust Research Governance Permission system is designed to:

A) provide a standardised approach for obtaining HSC Trust Research Governance Permission for health and social care research studies in Northern Ireland and to ensure compatibility with multi-centre research studies led by other UK nations.

B) To protect all those involved in research (participants, researchers, care organisation and employing organisation) by ensuring that all regulatory and governance approvals are in place and are adhered to.

1.3 Each HSC organisation is responsible for granting research permission for research studies.

All research applications must be submitted using the web-based **Integrated Research Application System (IRAS)** as the single system for applying for the permission and approvals of health and social care research in the UK. An IRAS account should be created by following the instructions on the website. IRAS can be accessed at: www.myresearchproject.org.uk

IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NRES/ NHS / HSC Research Ethics Committees
- Confidentiality Advisory Committee (England and Wales)
- National Offender Management Service (NOMS – England and Wales)
- Social Care Research Ethics Committee (England only)

It is recommended that new researchers should undertake the e-learning IRAS training programme available on the website under the Quick Links section. By doing so, this should familiarise applicants with the software and enable efficient navigation through the system.

1.4 There are two types of research applications, involving a number of different categories of studies:-

Single centre studies (involving only one HSC Trust in Northern Ireland, those requiring ethical approval and those which do not require ethical approval); and
Multi-centre studies (involving more than one HSC Trust in Northern Ireland or with one or more UK nations).

All categories of research applications (including single centre studies) will require E-Submission of the IRAS form via the IRAS system through the Central Booking System based in Manchester. Contact Telephone number is 0207 1048000 (Available 9am to 4.30pm on week days, excluding bank holidays).

1.5 HSC Trust Research Governance Permission is required if your research involves:

- Patients/clients (tissue, organs, data)
- Staff
- Resources (consumables, equipment)
- Premises (facilities, resources)

1.6 Research studies involving primary care (General Practitioners, Dentists, Opticians, Community pharmacists), are not the responsibility of HSC Trusts, *unless* the primary care premises are owned by HSC Trusts or staff involved in the research are employed by HSC Trusts.

1.7

2 Pre-Application Stage

It is important to establish that you are actually conducting research within HSC Trusts, rather than service evaluation/service development or clinical audit. (See http://www.hra-decisiontools.org.uk/research/ for information on defining research and decision tool). The following areas have been identified for the applicant to consider, prior, to submitting an IRAS application to HSC Trust Research Offices for research governance permission

Setting up a Research Study

2.1 When setting up a research study it is important to make contact with the HSC Trust Research Office at an early stage. Discuss key areas such as feasibility, funding, sponsorship, scientific review, identification of local Principal Investigator/Local Collaborator, and requirement for honorary research contracts/research placement agreements. These must be secured, prior to submitting IRAS applications for HSC Trust Research Governance Permission. This will ensure that relevant governance issues can be identified early in the process, avoiding delays in the later stages. For non-HSC Trust staff, it is advisable that researchers involving Universities/University students should similarly make early contact with the relevant HSC Trust Research Office, for advice (Appendix 1). Studies should be initiated and prepared in draft through the Integrated Research Application System. Draft applications can be transferred to members of the research team for review and, where applicable, to the relevant HSC Trust Research Office to review in terms of application for sponsorship and funding only.

Feasibility

2.2 The feasibility of all studies should be considered as part of the development of the study protocol, with particular reference to the patient/client population to be sampled and available resources. If the study requires input from support departments of HSC Trusts, e.g. Pharmacy, Laboratory, Medicine, Radiology/ Radiation Protection, contact must be made with the Heads of those Services/Departments to discuss feasibility and costs at an early stage. Details of contacts for support departments are available from

HSC Trust Research Offices.

Funding

2.3 Applicants should provide written evidence of funding arrangements for the research study. If funding has not been secured before submission for research governance approval, the funding body may require changes to the research study, which could result in the need to submit substantial amendments or even withdraw and re-submit the application. This is particularly important for studies that are not commercially sponsored and require substantial financial support from non-commercial bodies or HSC Trusts.

2.4 HSC Trust research governance permission for the conduct of research requires assurance that the study is properly funded with sufficient personnel, financial and material resources to ensure responsible conduct of the study until completion. This shall include an assessment on research, treatment and service support costs as well as impact upon the provision of care and services by the HSC Trust. All financial aspects of projects are reviewed by HSC Trust Finance staff before final research governance permission can be granted. It is extremely important that all financial implications to HSC Trusts are carefully considered at the outset of a project.

2.5 Researchers are reminded that research that requires access to the resources, patients, staff and/or premises of HSC Trusts will, in many cases, have cost implications for the HSC organisations concerned. Experience indicates that funding to cover these costs is often not included in grant applications, resulting in a range of potential or actual difficulties. These include:

- The Trust being unable to accommodate the research
- Research having to be stopped

2.6 Researchers are requested to ensure that grant applications in support of research studies involving HSC Trusts take account of these costs and include sufficient funds to cover them. Information on costings for HSC staff time, and resources can be obtained from Trust Research Offices.

Sponsorship

2.7 It is a requirement for all research to have a sponsor in accordance with the Research Governance Framework for Health and Social Care.

2.8 In addition, under the Medicines for Human Use Clinical Trials Regulations 2004 and the Amendments Regulations 2006, it is a legal requirement for all Clinical Trials of Investigational Medicinal Products (CTIMPs) to have a Sponsor.

2.9 Any research requiring the collaboration of the HSC Trust must have an organisation who has agreed to undertake the responsibilities of the research sponsor/co-sponsor. The sponsor takes responsibility for the initiation, management and financing (or arranging the financing of that research study). This involves ensuring the design of the study meets the required standards and that arrangements are in place to ensure appropriate conduct and reporting.

2.10 Prior to requesting any study approvals through IRAS (REC, R&D, MHRA etc) sponsorship arrangements must be in place. Where an external sponsor cannot be secured for a study, application may be made to a HSC Trust Research Office. If the HSC Trust is sponsoring your study the Trust must ensure that the study is of an appropriate scientific quality. If the study has been, or will be reviewed for scientific quality by an external funder it may not need further peer review. If the study will not be reviewed by an external funder, the HSC Trust Research Office will obtain a peer review.

2.11 The HSC Trust Research Office must verify that the sponsorship/co-sponsorship arrangements are appropriate for the study whether sponsored/co- sponsored by the HSC Trust or an external organisation. Once the sponsor is agreed, it is a formal requirement to have the sponsor either:

- Sign electronically authorise the "Declaration by the sponsor's representative" part of the IRAS application; or
- Provide a letter confirming their agreement to the "Declaration by the sponsor's representative" part of the IRAS application.

2.12 When making a sponsorship/co-sponsorship application to the HSC Trust Research Office the following should be submitted:

- Draft IRAS Form and IRAS SSI Form[1]
- Research Protocol (version control and date), including Participant Information Sheets and Informed Consent Forms, where applicable.
- External Referees or other scientific critique report (if available) or Funding Confirmation letter from a recognised funder completing peer review
- Peer review nominations (if external scientific critique not available)

2.13 Trust Research Office will review your study, complete a peer review if required, assess the appropriate sponsorship/co-sponsorship arrangements, initiate sponsorship/co-sponsorship agreements and negotiate contracts.

Scientific Review (Peer Review)

2.14 When making an application for HSC Trust Research Permission, the HSC Trust Research Office expects to receive a research study protocol that has already obtained a favourable scientific review (also known as peer review or scientific critique). The sponsor of the research is responsible for the scrutiny of the hypothesis, design, methodology and analysis of a proposed research study. This review should be carried out by independent experts. Arrangements for peer review should be commensurate with the scale of the research and the potential risks or burdens involved for participants.

Principal Investigator/Local Collaborator

2.15 Where a Chief Investigator is not based in a HSC Trust, a Principal Investigator/Local Collaborator should be identified for all participating Trusts. If you are unable to identify a suitable Principal Investigator/Local Collaborator, contact the HSC Trust Research Office.

Honorary Contracts/Research Placement Agreements

2.16 For research involving non-HSC Trust staff wishing to have access to HSC Trust patients/clients, staff, premises, it is a requirement that an honorary contract application/letter of access/research placement agreement be completed (along with any necessary pre-employment requirements for e.g. occupational health clearance, Access NI check, photographic evidence, etc.). It is advisable to make early contact with HSC Trust Research Offices as these applications may involve other HSC support departments – e.g. Human Resources and Occupational Health Departments.

Intellectual Property

2.17 All HSC bodies must identify, manage and exploit Intellectual Property (IP), arising from HSC research. The HSC R&D Division of the Public Health Agency established HSC Innovations as a regional service for the support and management of innovation and IP within the HSC. Further advice on IP for HSC R&D can be obtained via the HSC Trust Research Offices or by contacting www.innovations.hscni.net

Personal and Public Involvement (PPI)

2.18 Organisations have a statutory duty to involve service users and the public in the commissioning, planning and delivery of all Health and Social Care services. This process is known as PPI. Integrating PPI into the research process ensures that researchers prioritise topics that are important for service users, and formulate questions, processes and outcomes that are patient and public centered rather than solely researcher led. Engaging with PPI representatives as partners rather than research subjects has been shown to produce a range of benefits and impacts. It brings about benefits to researchers, PPI representatives themselves and to the wider community. In relation to engaging PPI representatives within specific research projects, it is recommended where no PPI contact is available to the researcher, to make contact with the local Trust Research Office who may be able to assist in identifying suitable contacts. There is also a

regional research group established within the Public Health Agency http://www.research.hscni.net/pier-ni-public-involvement-enhancing-research

Good Clinical Practice (GCP) Training

2.19 Any member of the research team conducting research involving Health and Social Care should have completed appropriate training, including GCP training for clinical trials and to provide HSC Trust Research Offices with certified evidence. Access to GCP e-learning and training can be obtained by contacting HSC Trust Research Offices who will provide a link to the NIHR GCP e-learning programme. GCP training must be updated every 3 years, or as indicated by Sponsor.

Disputes/Resolutions

2.20 Any concerns or dissatisfaction with the HSC Trust Research Governance Permission process must be addressed, in the first instance, to the Relevant HSC Trust Research & Development Manager. If a satisfactory outcome is not reached, then the relevant HSC Trust Director of Research & Development may be approached to resolve any outstanding issues. Any remaining issues can be addressed through the Executive Director responsible for Research and Development at Trust Board level.

3 Process of Submitting an IRAS E-Submission

3.1 Once the pre-application stage has been fully completed, please proceed to submit the IRAS form, together with supporting documents as per detailed guidance at www.myresearchproject.org.uk/help/contents/StepByStep_v2-0_20180628.pdf. **All** NHS/HSC study applications (single and multi-centre studies) are made through the e-submission of the IRAS Form and associated documents through the IRAS system and applications are booked in through the Central Booking Service (including studies which do not require a REC review).

IRAS e-Submission Process – summary

1. Complete the IRAS Form
2. Upload all applicable study documents to the IRAS Form checklist

3. Ensure the application is ready to submit and passes the verification step. The IRAS Form e-submission tab gives guidance on this, as noted in above link.
4. Book in the application for review using the Central Booking Service based in Manchester, Telephone 0207 1048000 (between 9am and 4.30pm on weekdays, excluding bank holidays). If the study requires Research Ethics Committee (REC review, the service will book the REC meeting slot at the same time as enabling e-submission. For non-REC studies the service will enable e-submission. Applicants will receive a confirmation email from the Central Booking Service.
5. Add the booking information to the first page of the IRAS Form.
6. Click the "E-submit application" button to submit the application.

NB. The Central Booking Service asks questions relating to the application in order to assign the application to the correct Research Ethics Committee reviewers if the Study requires ethical approval. The research applicant should make the call to the Central Booking System as the person making the call must understand what the study entails.

What happens after e-submission?

3.2 The system will automatically send the IRAS Form and associated documents to the lead nation to carry out NHS/HSC study-wide review. If applicable, the system also sends the application to the Research Ethics Committee for their review.

The IRAS Form e-submission tab displays a history which will show what has been submitted and when.

The person undertaking NHS/HSC study-wide review and the Research Ethics Committee, where applicable, will contact the applicant as the application goes through the review process.

If the application indicates that the study will have participating NHS/HSC organisations in other UK nations, the lead nation will share the application with national coordinating functions of the participating nations – for NI, this is the HSC Research Application Gateway.

Local HSC Trust Site Set Up

3.3 It is important for local site set up processes, that applicants should email the IRAS SSI form, checklist and associated documents, along with any local HSC Trust forms to the participating HSC Trust Research Offices, using the contact details in appendix 1.

APPENDIX 1

Research & Development Office
Belfast Health and Social Care Trust
Room 2010, 2nd Floor
King Edward Building
Royal Hospitals Site
Grosvenor Road
Belfast, BT12 6BA
Tel: 028 9063 6366
Email: ResearchApprovalTeam@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 3756 3755
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 and Social Care Trust
Bush House
Antrim Area Hospital
Antrim BT41 2QB
Tel: 028 94424653
Email: frances.johnston@northerntrust.hscni.net

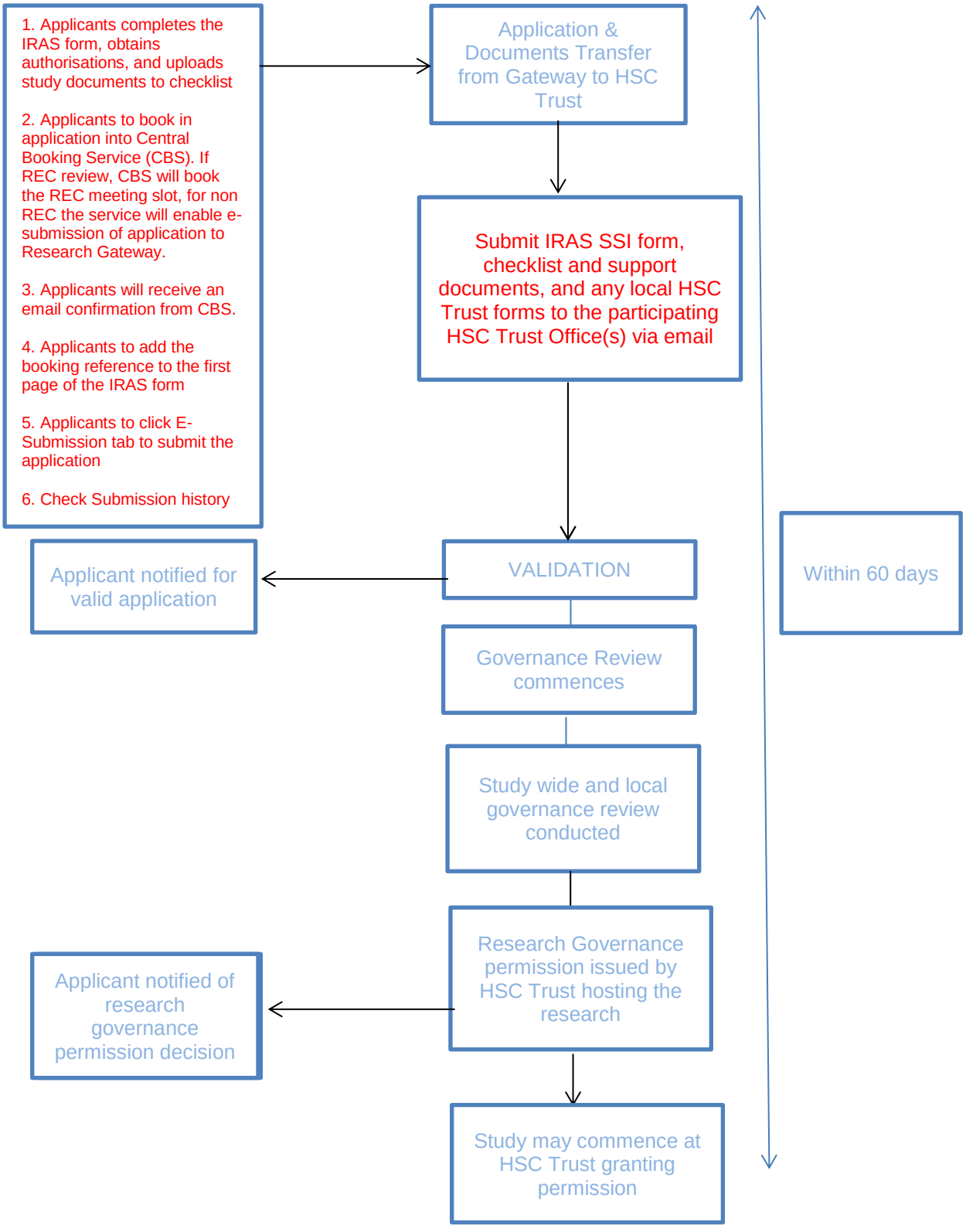
Research & Development office
Western Health and Social Care Trust
Clinical Translational Research & Innovation Centre (C-TRIC) Altnagelvin Area Hospital
Glenshane Road
Londonderry, BT47 6SB
Tel: 028 71611362
Email: sally.doherty@westerntrust.hscni.net

HSC R&D Application Gateway
CTRIC
Altnagelvin Area Hospital
Glenshane Road
Londonderry
Northern Ireland
BT47 6SB
Tel: (028) 71611126
Email: **research.gateway@hscni.net**

Appendix 2

HSC TRUST STUDY PROCESS OVERVIEW FLOWCHART

The flowchart for ALL research applications is as follows:



Appendix 3

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.

ARSAC Administration of Radioactive Substances Advisory Committee.

EDGE Research Management System Database**.**

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 behalf 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.

GTAC Gene Therapy Advisory Committee. GTAC has UK-wide responsibility for the ethical oversight of proposals to conduct clinical trials involving gene or stem cell therapies. The Committee also advises Ministers on the development and use of gene and stem cell therapies and works with other Government agencies with an interest in this area, such as the Medicines and Healthcare products Regulatory Agency (MHRA), the Health and Safety Executive (HSE) and the Human Tissue Authority.

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 coordination 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.

National Information Governance Board (NIGB) – Closed as from 31 March 2013 with functions transferred to the **Confidential Advisory Group** for England and Wales. (Privacy Advisory Committee responsible in Northern Ireland).

National Offender Management Service (NOMS) responsible for commissioning and providing offender services in the community and in custody in England and

Wales**. (**SEHSCT responsible for co-ordination of research involving prison services in Northern Ireland**).**

NHS National Health Service.

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

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 which collects the study data required 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.

NHS/HSC R&D Offices – Departments within HSC Trusts that are responsible for managing health and social care research.

NRES National Research Ethics Service.

NRES/NHS/HSC Research Ethics Committees responsible for protecting the rights, safety, dignity and well-being of research participants, facilitating and promoting ethical research that is of potential benefit to participants, science and society. (Office for Research Ethics Committees, Northern Ireland)

Primary care The provision of services by GPs and primary care teams in health centres and surgeries; and the services provided by independent contractor professions for e.g. opticians, dentists and community pharmacists.

Principal Investigator (PI) Where the research takes place in more than one site, this is the individual who is responsible for the 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.

Scientific review The scrutiny of the hypothesis, design, methodology and statistics of a proposed research study. The Research Governance Framework for Health and Social Care 2006 states that the review should be by experts in the relevant fields able to offer independent advice on the quality of the research study. Arrangements for review should be commensurate with the scale of research.

Social Care Research Ethics Committee appointed to review ethical components of research proposals, involving Social Care in England.

Sponsor The person who takes responsibility for initiation, management and financing (or arranging finance) for that trial/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 RMG office to verify that an application is complete and may be accepted for research governance approval.