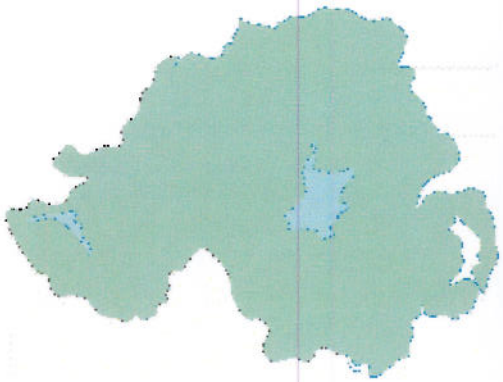
Health and Social Care

HSC Trust Research Governance Permission –

Guidance Note 1

Pre-Application Guidance for Applicants

How to Prepare an Application for Research Studies involving Secondary Care in HSC Trusts, Northern Ireland



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1 Introduction

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

A standardized permission process is managed separately by each of the five HSC Trust Research Offices for **single site** studies (see Appendix 1 for contact details). Applicants wishing to conduct a **multi-centre** study across a number of HSC Trusts must identify a lead Trust who is willing to undertake the global (generic) governance checks on behalf of the other participating Trusts. The local governance checks will be undertaken by each participating Trust. In order to identify a Lead Trust, please make contact with any one of the HSC Trust Research Offices (Appendix 1). For studies being initiated and led from one of the other devolved nations 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.

All research applications must be submitted to HSC Trusts by using the web-based Integrated Research Application System (IRAS).

IRAS

1.2 IRAS:

- Is a web-based system for applying for permissions and approvals for health and social care / community care research in the UK.
- Enables you to enter the information about your project once instead of duplicating information in separate application forms.
- Uses filters to ensure the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.
- Helps you meet regulatory and governance requirements.

1.3 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)
- Ministry of Justice
- NHS / HSC Research and Development offices
- NRES / NHS / HSC Research Ethics Committees

1.4 IRAS is just one element of a broader effort to reduce bureaucracy for researchers. IRAS can be accessed at: www.myresearchproject.org.uk, and an account should be created by following the instructions on the website.

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

1.5 It is hoped by adopting a streamlined approach to HSC research governance permission, that it will encourage researchers and enhance the attractiveness of Northern Ireland as a site for large scale research projects (commercial and non-commercial).

Furthermore, by forging links with the other research governance permission initiatives led in England, Scotland and Wales, the aim is to streamline the processes for cross border studies in an attempt to attract UK-wide studies opening in a more timely and efficient manner.

1.6 To carry out research within HSC Trusts in Northern Ireland, HSC Trust Research Governance Permission is required before a study can commence. HSC Trust Research Governance Permission is required if your research involves HSC Trust:

- Patients/clients (tissue, organs, data)

- Staff
- Resources (consumables, equipment)
- Premises (facilities)

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

(a) provide a streamlined and consistent approach for obtaining HSC Trust Research Governance Permission for secondary care studies in Northern Ireland, and

(b) 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.

Research studies involving primary care, 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.

2 Pre-Application Stage

Firstly it is important to clearly establish that you are actually conducting research within HSC Trusts, rather than service evaluation/service development or clinical audit. (See www.nres.npsa.nhs.uk or email: queries@npsa.nhs.uk). 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 in the early stages of the study development. Key areas of feasibility, funding, sponsorship, scientific review, identification of local Principal Investigator/Local Collaborator, and requirement for honorary contracts, **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 should similarly make early contact with the relevant HSC Trust Research Office, for advice. Projects 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 is available from HSC Trust Research Offices.

Funding

2.3 For externally sponsored and funded studies, applicants can proceed directly to IRAS submission, and should make immediate contact with the identified Lead HSC Trust Research Office/Local HSC Trust Research Office.

2.4 Applicants should provide written evidence of funding arrangements for the research study. If funding has not yet 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.

2.5 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 Trust Finance staff before final research governance permission can be granted. It is extremely important that all financial implications to Trusts are carefully considered at the outset of a project.

2.6 Researchers are reminded that research that requires access to the resources, patients, staff and/or premises of NHS/HSC Trusts will, in many cases, have cost implications for the 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 having to cover the costs from its own budgets
- The Trust being unable to accommodate the research
- Significant shortfalls in funding or overspends
- Research having to be stopped

2.7 Researchers are requested to ensure that ALL grant applications in support of research studies involving NHS/HSC Trusts take account of these costs and include sufficient funds to cover them. Information on costings for HSC staff time, access and resources can be obtained from Trust Research Offices (Appendix 1)

Sponsorship

2.8 Since April 2004 it has been a requirement for all research to have a sponsor. Under the Research Governance Framework for Health and Social Care all clinical research conducted in the NHS/HSC must have a Sponsor.

2.9 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.

2.10 Any research requiring the collaboration of the HSC Trust must have an individual or organisation willing and able 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.

2.11 **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 project, application may be made to a HSC Trust Research Office to sponsor/co-sponsor your project. If the HSC Trust is sponsoring your project it must ensure that it 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 review. If the study will not be reviewed by an external funder, the HSC Trust Research Office may facilitate the peer review of the project.

2.12 The HSC Trust Research Office must verify that the sponsorship/co-sponsorship arrangements are appropriate for a study whether the study will be 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 authorize the "Declaration by the sponsor's representative" part of the IRAS application; or
- Enclose a letter confirming their agreement to the "Declaration by the sponsor's representative" part of the IRAS application.

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

- Draft IRAS NHS R&D Form and IRAS SSI Form[1]
- Research Protocol (version control and date)
- 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)

2.14 Trust Research Office will review your project, 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)

2.15 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). For studies conducted by University staff and students, these will normally already have been subject to peer review. 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

2.16 Where a Chief Investigator is not based in a HSC Trust, a Principal Investigator/Local Collaborator must be identified for all participating Trusts – dependent on the contribution/collaboration required. If you are unable to identify a

[1] At this stage, the IRAS form does not need to be fully completed but should contain as much information as available at the time of sponsor request.

suitable Principal Investigator/Local Collaborator, contact the HSC Trust Research Office who may be able to assist in identifying a suitable member of staff for you to contact regarding their willingness to fulfill such a role.

Honorary Contracts

2.17 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 be completed (along with any necessary pre-employment requirements for e.g. occupational health clearance, Access NI). Further details of honorary contract applications can be obtained from the HSC Trust Research Offices, as local requirements may differ. It is advisable to make early application for honorary research contracts, as these involve other HSC Trust support departments – e.g. Human Resources and Occupational Health Departments. It is hoped that a HSC Research Passport or Regional HR process will be introduced to negate the need for duplication of checks and issuing of honorary contracts. It is envisaged that in many instances a letter of access may suffice, rather than an honorary contract. This work is in progress and being led by the R&D Managers in association with other stakeholders, to reach a resolution to streamlined honorary research contracts.

Intellectual Property

2.18 Encouraging and exploiting innovation is one of the strategic priorities for the HSC R&D Strategy "*Research for Health & Wellbeing 2007-12*". The importance of identifying, managing and exploiting innovation is also stressed in the Research Governance Framework for Health and Social Care 2006. Accordingly all HSC bodies must identify, manage and exploit Intellectual Property Rights (IPR), arising from HSC research. This requirement is reinforced in the Controls Assurance Standard for Research Governance. Criterion 13 of this standard, requires Trusts to supply evidence verifying that they have satisfactorily complied with these requirements.

2.19 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. HSC Innovations has the necessary professional resources

and funding to offer this essential support service to HSC Bodies, and all HSC Trusts have signed a Memorandum of Understanding to this effect with HSC Innovations. Further advice on IP for HSC R&D can be obtained via the HSC Trust Research Offices.

Personal and Public Involvement (PPI)

2.20 Organisations have a statutory duty to involve 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 centric 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.

Good Clinical Practice (GCP) Training

2.21 Anyone wishing to participate in research involving Health and Social Care must have completed GCP training and provide HSC Trust Research Offices with certified evidence. GCP training must be updated every 3 years, and is provided by the HSC Trusts on a regular basis.

Clinical Research Support Centre (CRSC)

2.22 The aim of the CRSC is to promote and support high quality research and development covering the spectrum of Health and Social Care activity from clinical practice to health and social services provision. The CRSC team can offer support at various stages of a research project from, planning a study, conducting a study and developing research skills. Other such services include Data Management services, clinical research monitors and training workshops. For further guidance, contact the Trust Research Offices.

Submitting the Application for R&D Governance Permission

2.23 Once all of the stages of pre-application are complete, the application may be formally submitted to the Trust Research Office. See Appendix 2 of this document for an overview of the research permission process and for details of application for a single site study or a multi-centre study. For full details of making an application see Guidance Note 2 "Submission of Application", available from Trust Research Offices.

Disputes/Resolutions

2.24 Any concerns or dissatisfaction with the HSC Trust Research Governance Permission process must be addressed, in the first instance, to the Lead HSC Trust/Local 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.

HSC Research Office Contact Details

2.25 Contact details for each HSC Trust Research Offices can be found at Appendix 1

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

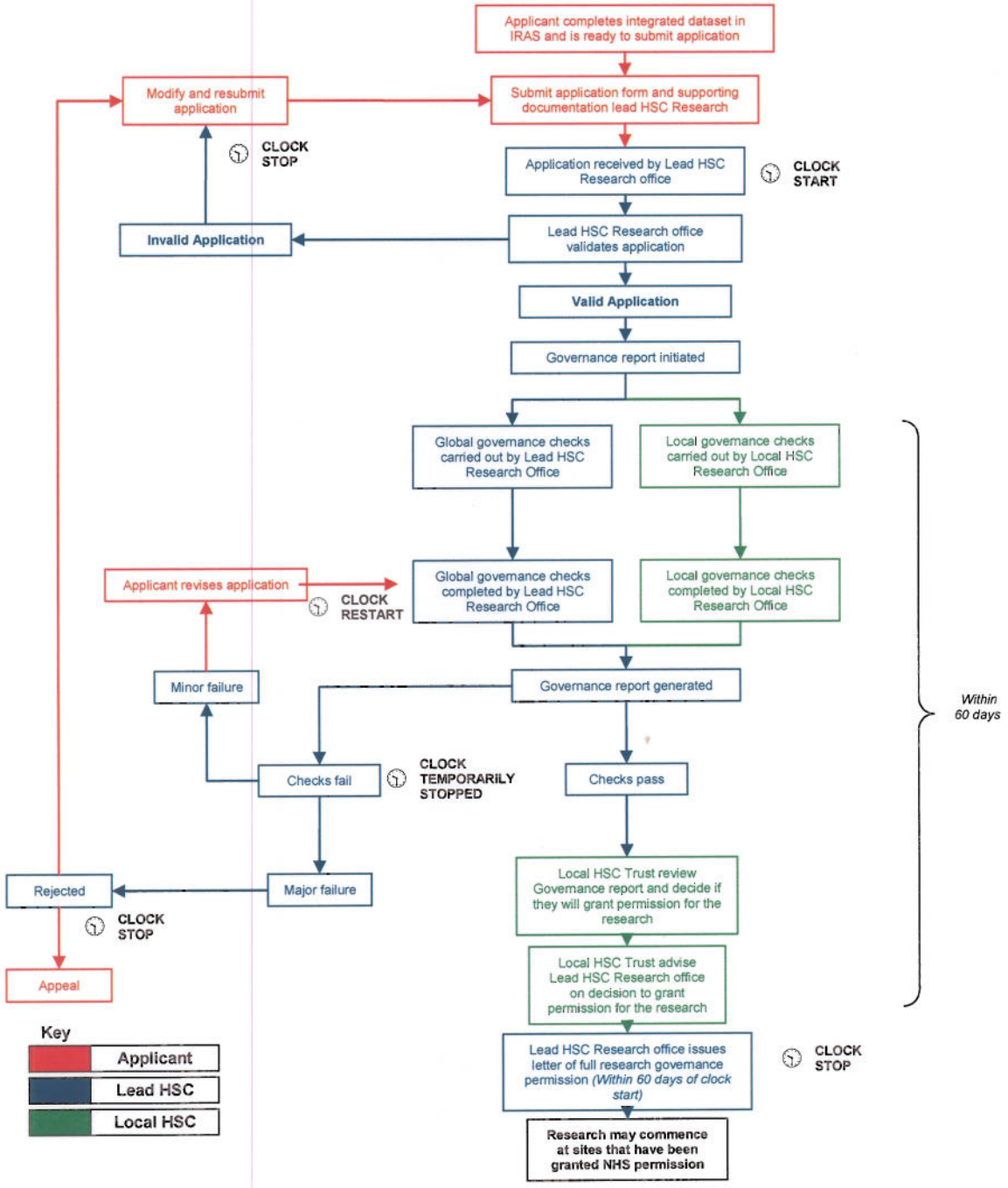
Research & Development Office
South Eastern Health and Social Care Trust
Room 19, Home 3
Ulster Hospital
Dundonald
Belfast BT16 1RH
Tel: 028 90553101
Email: Paul.Carlin@setrust.hscni.net

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 2

Flowchart of the HSC permission process overview

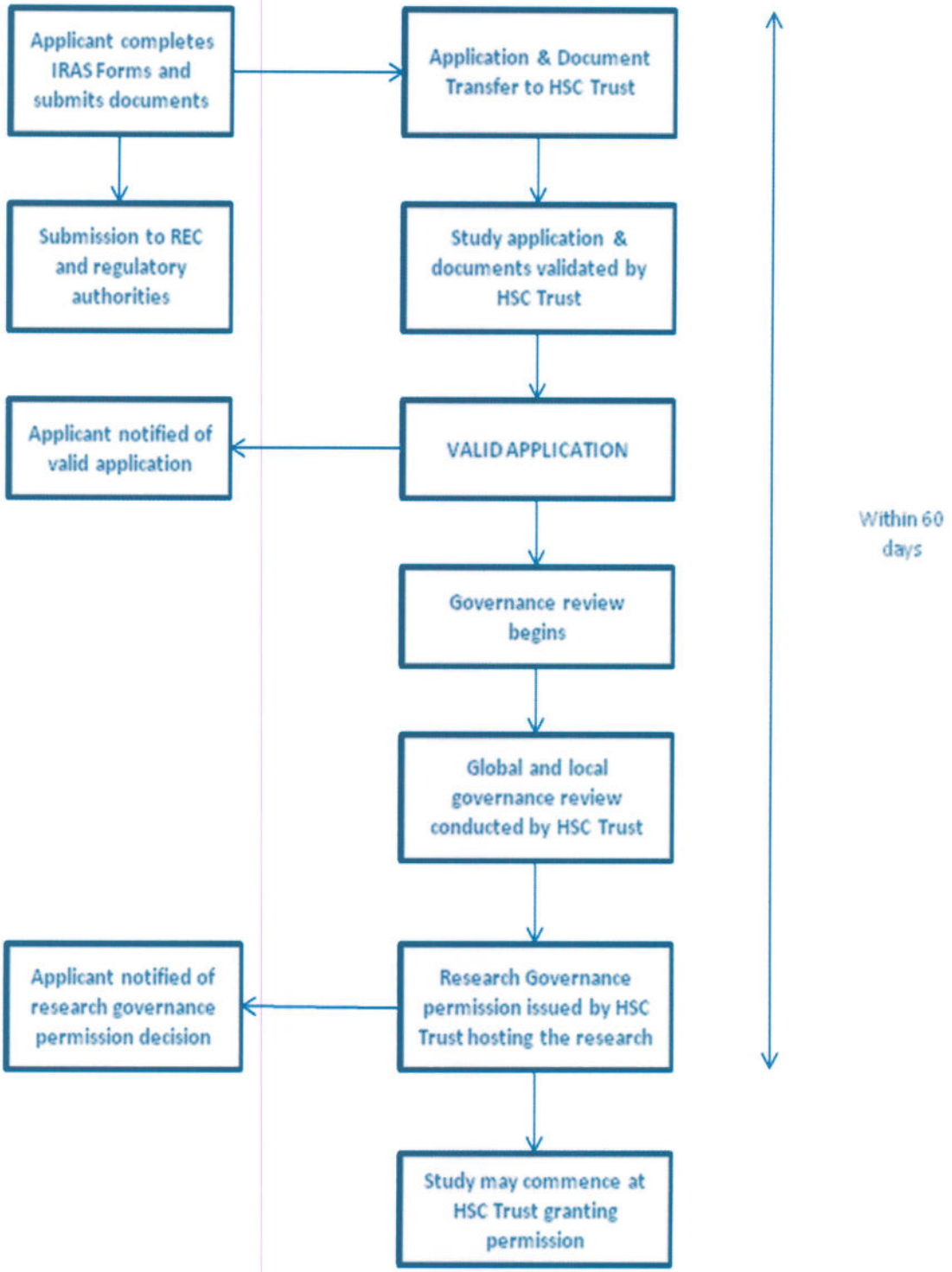


NB: For single site studies: the Local HSC Research Office undertakes responsibilities of both Local HSC Research Office and Lead HSC Research Offices

APPENDIX 2b

SINGLE HSC TRUST STUDY PROCESS FLOWCHART

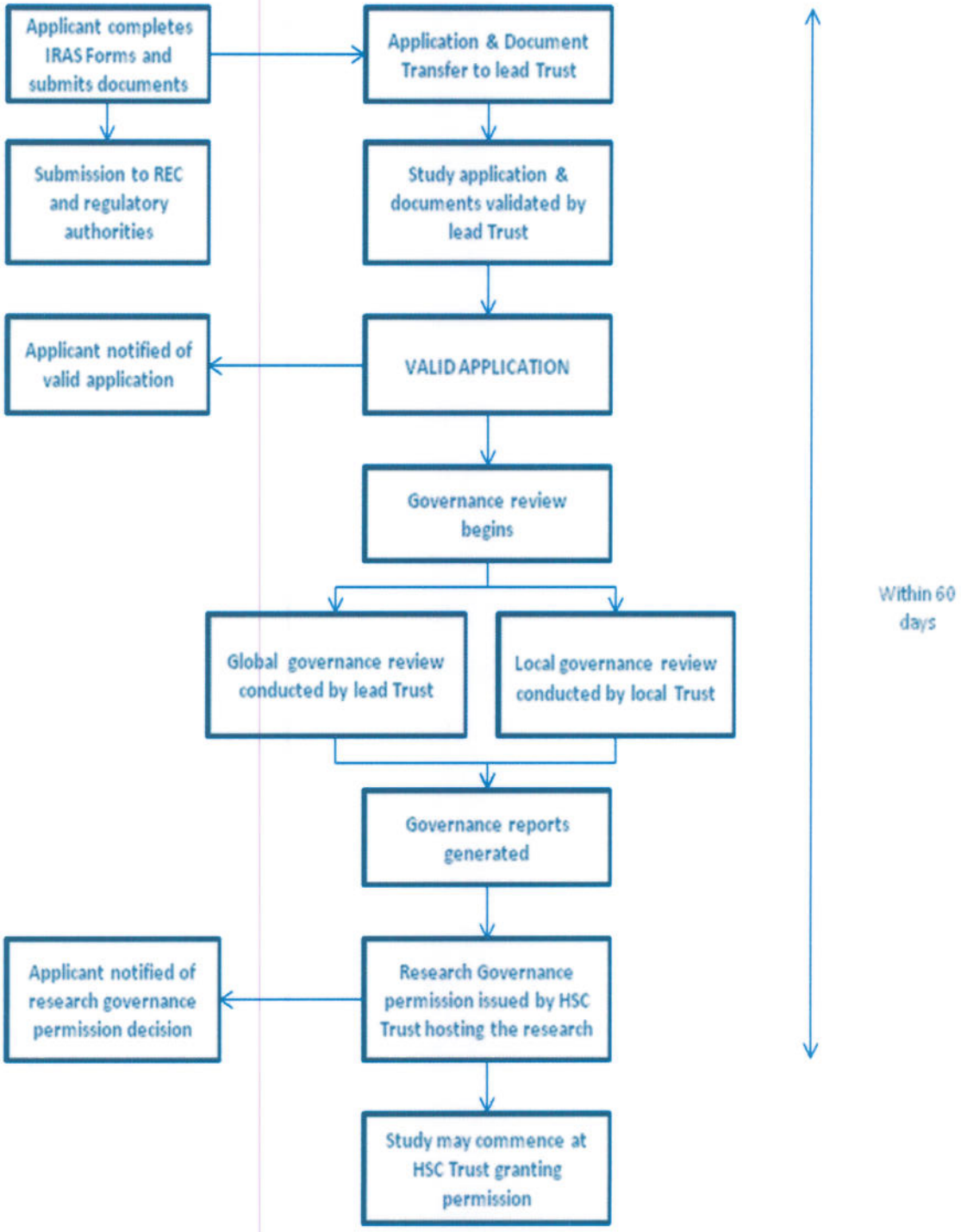
The flowchart for a number of research sites across a single HSC Trust or with a single research site within a single HSC Trust is as follows:



APPENDIX 2c

MULTI HSC TRUST STUDY PROCESS FLOWCHART

The flowchart for research studies with research sites across multiple HSC Trusts 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.

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.

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.

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.

NRES National Research Ethics Service.

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 like opticians, dentists and pharmacists.

Principal Investigator (PI) Where the research takes place in more then 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.

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 review.