Health and Social Care

HSC Research Application Guidance

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

Version 7.0
Updated: May 2020

Table of Contents

Appendices

1 Introduction

1.1 In accordance with the UK Policy Framework for Health & Social Care Research (2017), Research Governance compliance 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 system is designed to:

A) provide a standardized approach to HSC Trust Research Governance compliance for health and social care research studies in Northern Ireland and to ensure compatibility across the UK.

B) To protect all those involved in research (participants, researchers, care organisations and employing organisations) by ensuring that all regulatory and governance arrangements are in place, before formal confirmation of capacity and capability can be issued.

1.3 Each HSC organisation is responsible for research governance and to ensure that the study-wide and local governance reviews have been undertaken and confirmation of capacity and capability is issued, before a research study can commence. All research applications must be submitted using the web-based **Integrated Research Application System (IRAS)** www.myresearchproject.org.uk. IRAS:

- Is a single system of application to conduct 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 that the data collected and collated is appropriate to the type of study, and consequently the
- Helps you to meet regulatory and governance requirements

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)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)

- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NHS / HSC Research Ethics Committees
- Her Majesty's Prison and Probation Service (HMPPS)
- Social Care Research Ethics Committee

IRAS promotes feedback to improve its service user experience and applicants are asked to send their feedback to iras.queries@nhs.net.

It is recommended that new or novice researchers should undertake the e-learning IRAS training module available on the header tab on the IRAS website. By doing so, this should familiarise applicants with the software and enable efficient navigation through the system. New upgrades are regularly highlighted in purple on their opening page, together with additional help on the IRAS guidance tab.

1.4 There are two types of research applications, involving a number of different categories of studies, as described in the project filter:-

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 sites in other UK nations).

All categories of research applications (including single centre studies) will require online submission of the IRAS form and supporting study documentation using the online booking within IRAS, which replaces the telephone Central Booking Service (CBS), from 19 May 2020. This will allow applicants to book in their application and select the appropriate review bodies. The online booking service is quick and easy to use, and will be available 24 hours a day, seven days a week. Advice will be provided to applicants, where needed https://www.myresearchproject.org.uk/Signin.aspx

1.5 Formal Confirmation of Capacity and Capability is required from Trust Research Offices, if your research involves:

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

1.6 Research studies involving primary care (General Practitioners, Dentists, Opticians, Community pharmacists), are not the responsibility of HSC Trusts, *unless* HSC Trusts own the primary care premises or staff involved in the research are employed by HSC Trusts. Further advice can be found by contacting the relevant GP practice, details contained within the Research Site ODS codes section in IRAS, or the Northern Ireland Clinical Research Primary Care Network *NICRNPCGenQuery@nicrn.hscni.net*

1.7 This guidance has been written as two distinct stages, one to support the important pre-application stage of research studies, and the second being the actual submission process of an IRAS application for a research study.

2 Pre-Application Stage

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

Setting up a Research Study

2.1 When setting up a research study it is important to make contact with the appropriate HSC Trust Research Office(s) 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, where applicable. These must be discussed and agreed, prior to submitting an IRAS application to HSC Trusts. This will ensure that relevant governance issues can be identified early in the process, thus avoiding unnecessary delays in the later stages. For non-HSC Trust staff, it is recommended that researchers involving Universities/University students should similarly make early contact with their respective University Research Office or relevant HSC Trust Research Office, for

advice (Appendix 1). Studies should be initiated and prepared in draft through IRAS, thus saving unnecessary amendments, following online submission. Draft applications can be transferred by the project owner to members of the research team for discussion and review and, where applicable, to the relevant HSC Trust Research Office or University Research Office to review in terms of application for sponsorship and funding.

Feasibility

2.2 The feasibility of all studies should be considered as part of the development of the study protocol and design of the study, 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, Radiology/ Radiation Protection, etc., 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 of your application, 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 significant financial support from non-commercial bodies or HSC Trusts. Support from Trust Finance can be obtained by contacting the Trust Research Office for contact details. This is particularly important at grant application stage and defining the protocol.

2.4 Compliance with research governance 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 formal confirmation of capacity and capability can be issued. The Schedule of Events assists with this process. It is extremely important that all financial implications to HSC Trusts be carefully considered at the outset of a project. Again details of attribution of research costs must be considered in accordance with the Accord guidelines https://research.hscni.net/funding-costs-research-acord-principles. For research activity in Northern Ireland, funding of NHS or HSC Support Costs (Service Support Costs) is the responsibility of HSC R&D Division, subject to satisfactory review and available budget. You should apply for funding of Service Support Costs by contacting the Public Health Agency Research Department as early as possible in your application process. See guidance on managing costs onhttps://research.hscni.net/sites/default/files/Managing%20Costs%20associated%20with%20research%20in%20NI%20v1120.pdf

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 downstream. 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. Further advice on costings for HSC staff time, and resources can be obtained from Trust Research Offices and details of funding opportunities from the Public Health Agency Research Division https://research.hscni.net/.

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

- Research Protocol, including Participant Information Sheets and Informed Consent Forms (all with version control/date), 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/agreements, as required.

Scientific Review (Peer Review)

2.14 The HSC Trust Research Office expects to receive a research study protocol that has already obtained a favorable 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, or Local Collaborator should be identified for all participating Trusts. If you are unable to identify a suitable Principal Investigator/Local Collaborator, please contact the HSC Trust Research Office for assistance.

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 or external organisations and may require considerable time to complete – e.g. Human Resources and Occupational Health Departments. (It is recognised that honorary contracts/placement agreements/research passports is an area that can cause confusion for researchers working across multiple NHS/HSC organisations, and therefore has been identified as a UK service improvement project to commence).

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 intellectual property within the HSC, together with advice on research contracts and agreements. Further advice can be obtained by contacting the relevant HSC Trust Research Office or direct contact via 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 prioritize 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, contact with made 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, as appropriate. 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. Other forms of accredited training and webinars are also available on the Health Research Authority (HRA) website - www.hra.nhs.uk/planning-and-improving-research/learning

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.

Pharmacy Assurance

2.21 Pharmacy Assurance coordinates a standardised single technical pharmacy review for eligible studies across the UK. The completed review can be used by all participating NHS/HSC sites across the UK to support local capacity and capability assessments and study set up in their pharmacy departments. The benefits for sponsors/applicants is that there are few duplicated queries from multiple sites and guidance on the information requirements for the pharmacy review is included in the Local Information Pack, which can lead to sites agreeing to participate sooner and help streamline study set up. Pharmacy assurance should be completed in advance of the IRAS application online submission. For further details see https://www.myresearchproject.org.uk/help/hlppharmacyassurance.aspx

3 Process of Submitting an IRAS Application

3.1 Once the pre-application stage has been fully completed, please proceed to submit the IRAS form electronically, together with supporting documents as per detailed guidance at www.myresearchproject.org.uk/help/contents/StepByStep_v2-0_20180628.pdf. **All** NHS/HSC/HSC study applications (single and multi-centre studies) are made through the online submission of the IRAS Form and associated documents and checklist through the IRAS system. All applications must now be booked online in IRAS. The online booking will be available to applicants 24 hours a day, seven days a week. Guidance is available within IRAS as well as a video youtube link to support applicants booking https://youtu.be/_RNRAK44nno

IRAS Online 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 online booking in IRAS. The applicant will be guided and provided with a list of questions to answer and to book their choice of REC, where required. Applicants will receive a confirmation email to confirm the application has been booked to the relevant review bodies, and to continue to submit their application.
5. Click the “E-submit application” button to submit the application.

NB. It is important to take time and answer the questions fully 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 booking as the person that understand what the study entails.

What happens after online submission in IRAS?

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 function (NCF) of the participating nations – for NI, this is the HSC R&D Application Gateway.

Local HSC Trust Site Set Up

3.3 It is important for local site set up processes, that applicants should email the UK Local Information Pack, along with covering email template to Trust Research Offices (see Appendix 1 for contact details). The UK Local Information Pack contains an **Organisation Information Document** that has replaced the **IRAS Site Specific Information form (SSI)**, previously used in Northern Ireland and Scotland, and the **Statement of Activities** (SoA) that was used in England and Wales. The Organisational Information Document is required as part of the UK Local Information Pack and there is a version for both commercial and non-commercial research. A number of Questions and Answers have been provided to support the implementation of the UK Local Information Pack both for applicants and for research office staff - see UK Local Information Pack: Questions and Answers www.nhsresearchscotland.org.uk/services/uk-wide-working/enter-title-here

For more detailed information and guidance on the UK Local Information Pack please also visit IRAS Help www.myresearchproject.org.uk/help/hlpsitespecific.aspx In summary, an overview of the UK Local Information Pack can be found at Appendix 2.

As stated previously, it is recommended as good practice that you make early contact with the Trust Research Office(s) to consider the issues outlined in the pre-application stage. Following confirmation of regulatory approvals and study-wide governance review being in place, this will enable Trust(s) to formally confirm capacity and capability, by email communication, and to agree with the sponsor/applicant the date when the study can commence.

3.4 Finally, an overview of the Trust Research Process can be obtained at Appendix 3.

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
The Maples
Craigavon Area Hospital
68 Lurgan Road, Portadown
Co Armagh, BT63 5QQ
Tel: 028 3756 3755
Email: Research.Office@southerntrust.hscni.net

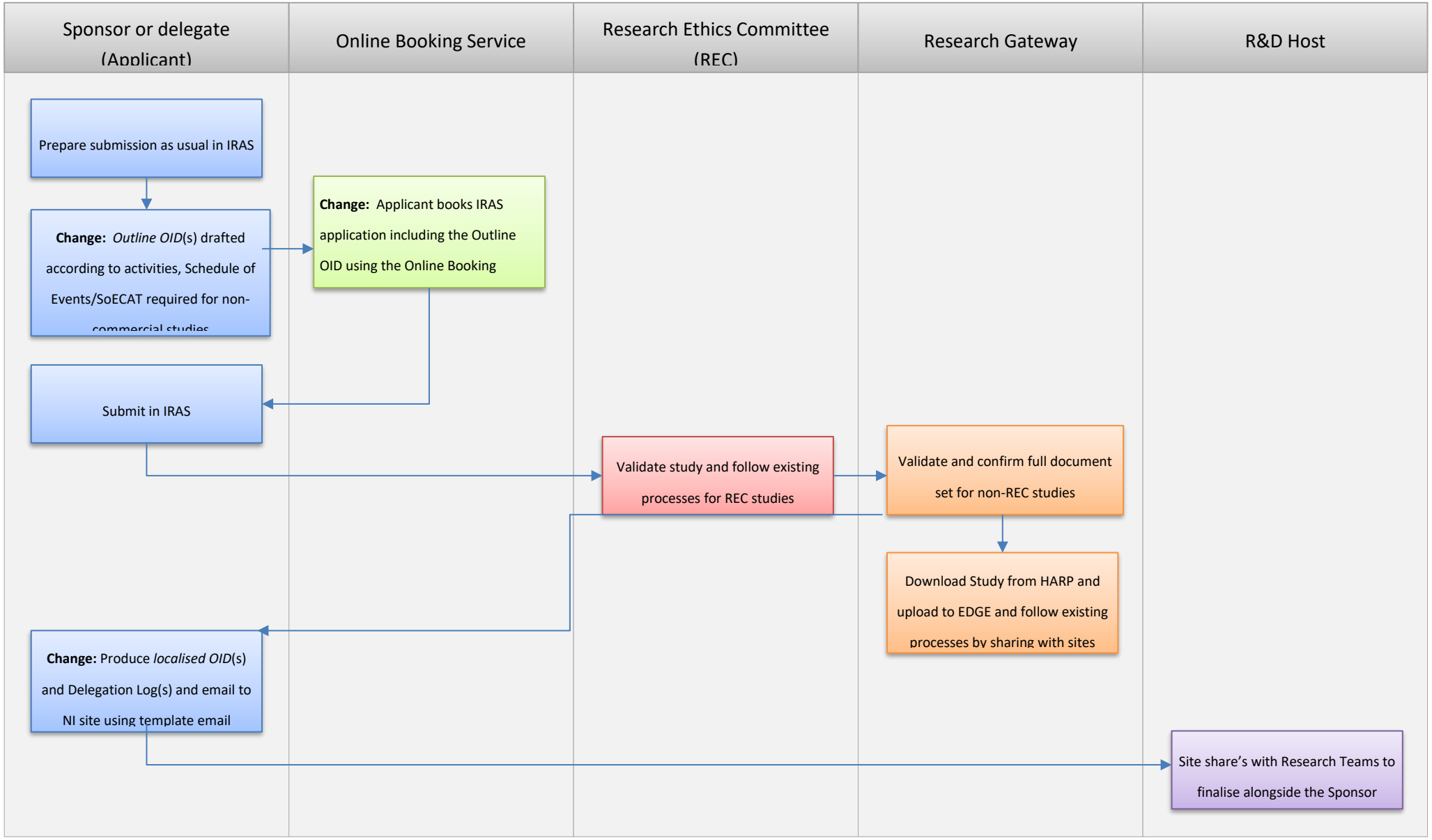
Research & Development Office
South Eastern Health and Social Care Trust
Room 19, Home 3
Ulster Hospital
Dundonald
Belfast BT16 1RH
Tel: 028 90553275
Email: Research.Development@setrust.hscni.net

Research & Development Office
Northern Health and Social Care Trust
Room 3
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: Research.Office@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
Local Information Pack – Overview for Northern Ireland



Summary of stages of completion

IRAS Submission

- Outline
- Part completed
- * Questions completed
- If sites are undertaking different activities, more than one will be required

Localisation

- Sponsor completes with known information
- Will differ across studies

Agreement

- Finalise together
- ^ completed by site

HSC Health and Social Care

Ymchwil Iechyd a Gofal Cymru Health and Care Research Wales

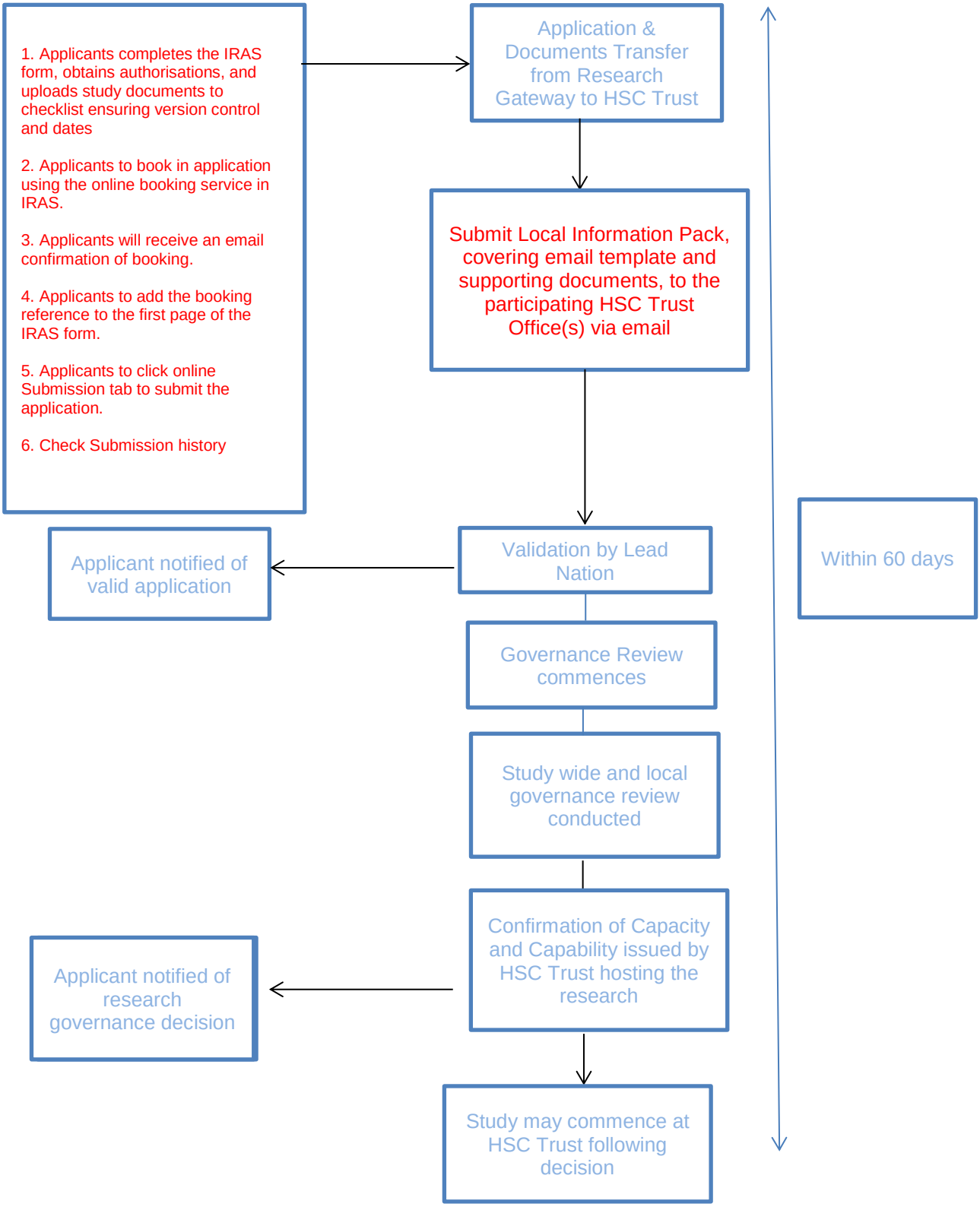
NHS SCOTLAND NHS RESEARCH SCOTLAND

NHS Health Research Authority

APPENDIX 3

HSC TRUST STUDY PROCESS OVERVIEW FLOWCHART

The flowchart for ALL research applications is as follows:



Appendix 4

Glossary

Amendment A change made to the terms of an application for NHS/HSC 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.

Confirmation of Capacity and Capability Formal confirmation of capacity and capability is the mechanism through which a participating NHS/HSC organisation informs the research sponsor (or their nominated representative) that the organisation is ready and able to commence research project activities.

EDGE Research Management System national database**.**

Funder The organisation providing the funding for the research study.

Governance checks A number of study-wide and local 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.

HSC R&D Application Gateway The R&D Application Gateway acts as the national co-ordinating function for Northern Ireland, that co-ordinates the study-documentation, and subsequent amendments, and uploads same to EDGE, the national research management database, used by Trust Research Offices. The Gateway's role is to facilitate and support the application process by working in partnership with the HSC Trusts and Sponsors/applicants, to ensure that all research applications, including amendments, are managed in a timely and efficient manner.

IRAS Integrated Research Application System.

IRAS Form This form provides all the relevant project-wide information, appropriate to the study type/category of research, and enables the study to be assessed for study-wide governance and appropriate regulatory approvals.

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 study.

Local Information Pack This is the specific information relevant to the site type to provide local details and requirements of the study to an NHS/HSC organisation. It comprises either a commercial or non-commercial Organisation Information Document and supporting documents, alongside a covering template email. The sharing of the Local Information Pack enables the research site to have a facilitatory conversation with the Sponsor/applicant to fully capture the activities required at each site to enable the site to provide confirmation of capacity and capability to deliver the study.

Local governance checks The checks required to be undertaken by an individual NHS/HSC organisation in respect of the study. These must be conducted by each NHS/HSC 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/HSC National Health Service, Health and Social Care.

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

NHS/HSC/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/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.

ORECNI Office for Research Ethics Committees, Northern Ireland, responsible for independent ethical review of applications in accordance with NRES standard operating procedures.

Organisation Information Document The outline Organisation Information Document is completed by the sponsor or authorised delegate and submitted with the IRAS application. It provides key information to facilitate the regulatory review of the submission and forms the basis from which localised Organisation Information Documents are then created in a partnership between the sponsor and research site. There are two versions, one for commercial studies and one for non-commercial studies.

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. PI responsibility is delegated by the Chief Investigator to perform duties at the site. A delegation log is used to document the responsibilities.

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.

Supporting documentation All documents associated with the main application.

Validation A check carried out by the Lead nation to verify that an application is complete and may be accepted for research governance permission/confirmation of capacity and capability.