

**THE NATIONAL INSTITUTE FOR HEALTH
RESEARCH**

RESEARCH SUPPORT SERVICES FRAMEWORK

***STREAMLINING THE
MANAGEMENT AND GOVERNANCE OF
R&D STUDIES IN THE NHS***

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1. INTRODUCTION

- 1.1. In May 2011, the Government launched the NIHR Research Support Services *“to facilitate consistent local research management and greatly improve performance”*¹.
- 1.2. The National Institute for Health Research (NIHR) has adopted the Research Support Services framework for local health research management. This framework of good practice will enable front line staff to collaborate in offering consistent professional streamlined services to support clinical research in the NHS in England.
- 1.3. This document introduces the framework and its standard operating procedures and associated tools for research management.
- 1.4. The NIHR expects that NHS organisations will be able to show they are using this framework when undertaking NIHR adopted research studies (NIHR portfolio studies). NHS and other organisations are encouraged to apply the same principles to non-portfolio studies to promote uniformity and consistency of practice. This framework can apply to all types of research in the NHS.
- 1.5. This framework advocates a proportionate approach to managing local operational risks associated with a particular study design. The standard operating procedures (SOPs) and tools have been developed with stakeholders and are based on existing good practice used in the NHS.
- 1.6. NHS organisations (Trusts, Foundation Trusts and those providers working with the NHS to deliver care) may already have, and can continue to use relevant SOPs provided they meet the requirements of this framework.

How to use this document

- 1.7. We recommend you read this document before using the appropriate SOP guidelines and tools. In particular:
 - Section 2 should be read by participating and sponsoring organisations.
 - Section 3 contains additional information for participating organisations.
 - Section 4 contains additional information for sponsoring organisations.
 - Sections 5 and 6 should be read by participating and sponsoring organisations.
- 1.8. You can use the framework electronically or print the documents to use in a ring binder (with annexes) as a desktop reference guide. The electronic version on the NIHR web site² follows the same structure.

¹ The Governments Plan for Growth – http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf

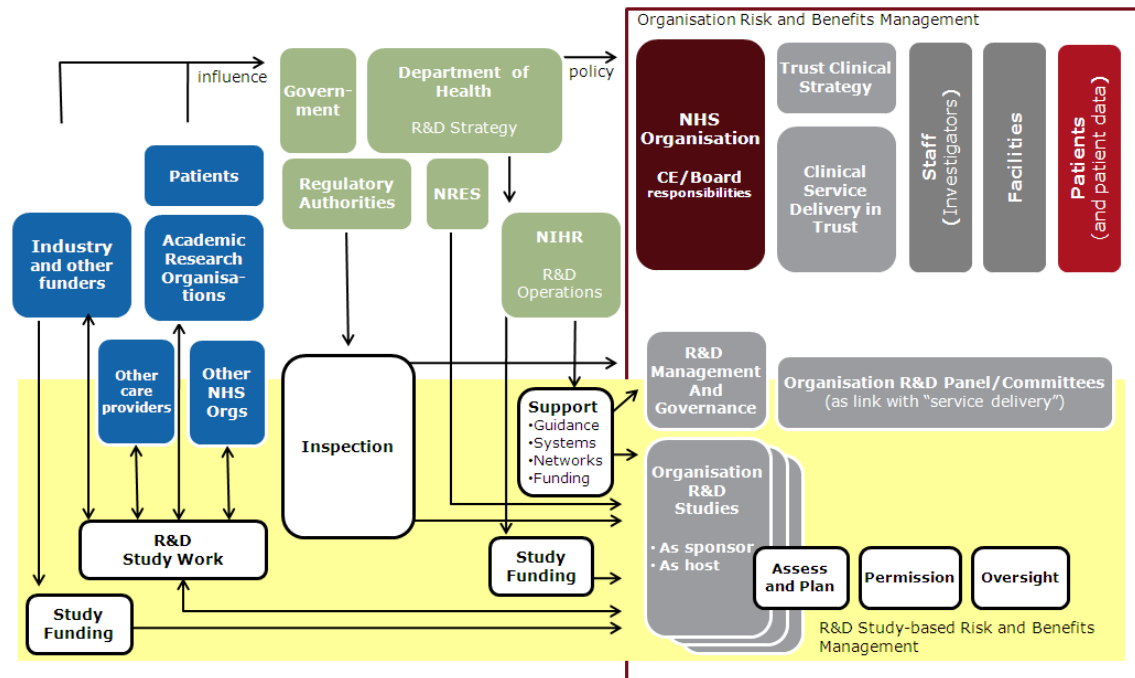
² http://www.nihr.ac.uk/systems/Pages/Research_Support_Services.aspx

Background

- 1.9. Health research and development (R&D) is core business for the NHS. It plays a vital role in improving health outcomes and the quality of care. It is a core element of the NHS Operating Framework. Research studies enable clinicians and researchers to develop new treatments and resolve uncertainty about existing treatments. They enable patients to benefit from access to new treatments. NHS organisations are expected to demonstrate their contribution to R&D in Quality Accounts and in outcomes from 2012.
- 1.10. R&D across the NHS is central to the UK's international reputation as a leader in life sciences. The work of academic researchers and the pharmaceutical and medical devices sectors depends on it. They are keen to use the experience within the NHS and the access to NHS patients to support their studies, provided they can rely on consistent and effective research management.
- 1.11. Health R&D is highly regulated. Clinical trials, medical device studies, use of patient data, professional qualifications, access to and treatment of NHS patients and other aspects of R&D studies are regulated by EU directives, UK legislation and professional standards of good practice. The Research Governance Framework for Health and Social Care³ describes the overarching framework within which R&D studies are delivered within the NHS.
- 1.12. In today's NHS, the role of the 'Research Manager' in an organisation is multi-faceted. A Research Manager is typically the person with delegated responsibility for making sure that the NHS organisation fulfils its regulatory requirements as an autonomous legal entity. They also work alongside the responsible senior investigator to facilitate the local management of the study and protecting the integrity of the study on the site. In some cases, they have to manage potential conflicts of interest between this support role and their role in assuring compliance with good governance.
- 1.13. This document uses the terms 'Research Manager' and 'R&D office' for the responsible person / team acting on behalf of the organisation in matters relating to R&D management. The Chief Investigator (CI) (working with the sponsoring organisation) or Principal Investigator (PI) (at a participating organisation) is responsible for the conduct of the study on behalf of the sponsor or participating organisation. Some responsibilities of the Research Manager / R&D office may be delegated to a joint office or an alliance organisation or a NIHR Clinical Research Network (NIHR CRN) by agreement of the organisation's Chief Executive or Board.
- 1.14. This document uses the term 'NHS organisation' to mean a NHS body (e.g. NHS Trust, Foundation Trust) or other organisation working with or on behalf of the NHS involved in R&D studies.
- 1.15. The guidelines do not specify 'who' undertakes specific roles (Trust, NIHR CRN, etc) but identify those activities for which the organisation is accountable. The NIHR expects organisations to have access to relevant competencies internally or externally, for example via networks and alliances. The guidelines are intended to refer to the person authorised to undertake each role.
- 1.16. The R&D stakeholder landscape is complex. Figure1 shows the different stakeholder perspectives in the R&D landscape.

³ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

Figure 1: R&D stakeholders have different perspectives



- 1.17. NHS organisations are legally responsible for their R&D activity including the safety of their staff and patients. The NIHR Research Support Services sets the organisation's management and governance in a framework that aligns it with the responsibilities of other stakeholders such as sponsors, investigators, regulators and clinical services.
- 1.18. The NIHR Research Support Services framework includes tools for the Research Manager / R&D office that support early and better collaboration with the investigators and sponsor to facilitate greater efficiency in the delivery of health R&D through:
 - a. for participating organisations, a way to assess local operational risks and to manage them proportionately throughout the NHS Permission process and study delivery. This rapid and early initial assessment enables the organisation to quickly determine if there are likely to be any issues that will delay giving NHS Permission or undertaking the study at the site. This supports sponsors and investigators by enabling R&D studies to be set up and started in a timely way.
 - b. for sponsoring organisations, a way to assess and proportionately manage sponsoring risks. This supports the investigators and protects the interests of the organisation in a timely way.
 - c. the use of a consistent and streamlined set of SOPs for governance of studies across organisations. This can be viewed as an 'implementation toolkit' for the Research Governance Framework.
- 1.19. The benefits of this NIHR Research Support Services framework are to:
 - a. provide a consistent view of the overall process for all stakeholders (Trusts, networks, sponsors, investigators, regulators, etc). In particular to describe the role of the Research Manager in managing operational risks on behalf of the organisation and investigators,
 - b. prompt the responsible Research Manager and the local PI to work together from the outset when undertaking study set-up and NHS Permission,
 - c. provide clarity on responsibilities across activities. In particular to identify the appropriate person(s) responsible for resolving issues,
 - d. differentiate between R&D support roles and governance responsibilities (including those roles and responsibilities delegated to networks and alliances),
 - e. raise the visibility of Research Managers and research governance in NHS organisations,

- f. promote early focus on proportionate management of operational risks – that is, risks associated with a study and the organisation's capabilities to manage the risks,
 - g. provide a clear plan for the Research Manager on how to complete the NHS Permission process in a reasonable time (and quickly highlight issues that could cause delay),
 - h. better support study feasibility and set-up activities. In particular to provide a clear and early indication to the sponsor / Chief Investigator on the likely outcome of the NHS Permission process,
 - i. continue to support parallel processing for study approvals, governance and local set-up activities,
 - j. remove excessive preparation activities undertaken by participating organisations during the NHS Permission process and so avoid delays in giving NHS Permission.
- 1.20. The outcomes of the approach described in the framework and supporting documents and tools, which benefit investigators, clinicians, patients, sponsors and research managers, are to:
- a. encourage more organisations to become involved in health R&D,
 - b. streamline the processes to enable studies to be set-up and started quicker,
 - c. encourage proportionate risk management decisions and activities.

Purpose of this document

- 1.21. This document describes the NIHR Research Support Services framework supporting proportionate management and governance of R&D studies.
- 1.22. It provides guidelines for NHS organisations to develop a set of consistent and streamlined standard operating procedures for all types of studies (for example, regulated clinical trials (Clinical Trials on Investigational Medicinal Products) , medical devices studies, quantitative studies, surveys, etc). It describes specific tools used by these SOPs including the R&D Operational Capability Statement and the study planning tools.
- 1.23. It is expected that these SOPs are used to manage operational risks in a way which is proportionate to study risks.
- 1.24. The SOP guidelines are intended to be applicable to all NHS organisations (including acute, mental health and primary care settings and organisations working with the NHS).
- 1.25. This document is intended to be used by Research Managers and staff within the R&D office in NHS organisations involved as sponsoring or participating organisations for managing governance SOPs.
- 1.26. This document should be used by other R&D stakeholders including investigators, commercial and non-commercial sponsors, academic research organisations, Clinical Research Networks and NHS organisation (Trust) senior management and staff who need to know:
- a. the R&D landscape and the role of the Research Manager,
 - b. how these processes join up with other processes in these organisations,
 - c. how they can collaborate effectively with the Principal Investigator, the Research Manager and the R&D governance team to further streamline processes and timelines.

Structure of this document

- 1.27. This document provides a central reference point for context and instructions to help you understand how to use specific guidelines.
- 1.28. Section 2: Overview of Research Support Services provides an introduction to the framework and the R&D Operational Capability Statement used by all organisations involved in research.
- 1.29. Section 3: Participating Organisation Guidelines provides further information on the participating organisation standard operating procedures and the Participating Organisation Study Planning Tool.

- 1.30. Section 4: Sponsoring Organisation Guidelines provides further information on the sponsoring organisation standard operating procedures and the Sponsoring Organisation Study Planning Tool.
- 1.31. **You may find it useful to read the information for both sponsoring and participating organisations. Effective use of this framework relies on the key people understanding both research management perspectives whichever role they undertake themselves.**
- 1.32. Section 5 contains guidance on how to use the SOP guidelines and templates provided in annexes.
- 1.33. Section 6 outlines the NIHR expectations on using the framework.

Acknowledgements

- 1.34. The guidance has been developed with the significant support of Research Managers across the NHS in acute, mental health and primary care organisations and in joint NHS academic R&D offices. It is based extensively on existing good practice in the NHS and has been refined and reviewed with the involvement of representatives from industry, universities, regulators and investigators.
- 1.35. The framework has been developed under the guidance of an external reference group involving senior level representation of chief executives and R&D management from NHS Trusts, regulatory authorities, the pharmaceutical and medical devices industries, university and academic investigators, NIHR and the NIHR CRN.
- 1.36. We gratefully acknowledge the contributions, personal time and the materials provided by all concerned during the development and checking of this guidance.

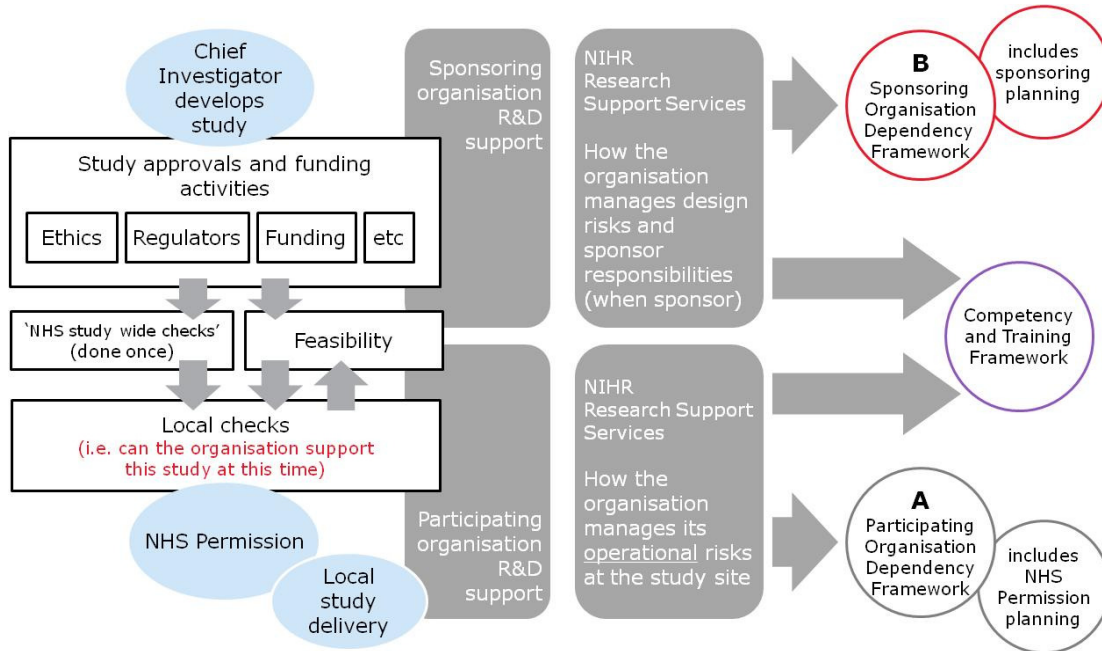
2. OVERVIEW OF RESEARCH SUPPORT SERVICES

This section is applicable to both participating and sponsoring organisations.

Introduction to the framework

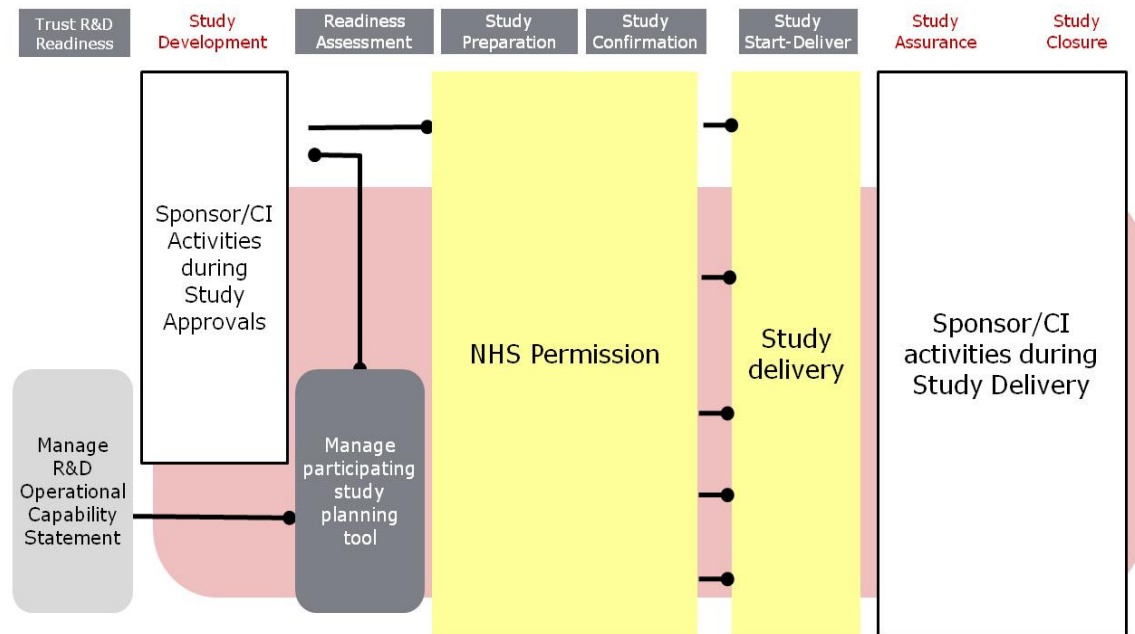
- 2.1. The NIHR Research Support Services framework provides standard operating procedure (SOP) guidelines for NHS organisations wanting to participate as a host research site (as a participating organisation) and for NHS organisations intending to sponsor a study (see figure 2).

Figure 2: NIHR Research Support Services provides a consistent framework for Research Managers and other stakeholders



- 2.2. The guidelines for **sponsoring organisations** address the governance procedures during the R&D approvals process and study management / oversight across all sites involved in the study.
- 2.3. The guidelines for **participating organisations** address the governance procedures during the NHS Permission process at the specific site and study oversight by the site during study delivery.
- 2.4. Information on research management staff competencies and training to support the use of the guidelines and tools is available on the NIHR website.
- 2.5. The SOP guidelines and tools are described in a way which considers the key activities in the typical R&D study lifecycle. They are called 'SOP dependency frameworks' because they show how processes and outcomes are dependent on earlier processes or outcomes.
- 2.6. Figure 3, shows the key stages (from left to right) used in the SOP dependency frameworks (using the participating organisation perspective as an example).

Figure 3: The SOP Dependency Framework provides a high-level overview of the R&D life cycle from a participating organisation perspective



2.7. These stages are:

- a. **Trust R&D Readiness:** The preparatory work undertaken by **any** NHS organisation to support health R&D (such as training and development, planning, etc) and which is independent of specific studies. It includes developing the 'R&D Operational Capability Statement'.
- b. **Study Development:** The activities undertaken by the investigator / sponsor in defining a study, gaining approvals and identifying suitable sites (feasibility).
- c. **Readiness Assessment:** The initial assessment of a new study by a participating organisation in order to start to identify and manage operational risks associated with local capabilities and capacity. It includes use of the study planning tool.
- d. **Study Preparation:** The activities by a participating organisation to prepare for a new study and which need to be managed to enable the organisation to provide NHS Permission to undertake the study on site.
- e. **Study Confirmation:** The decision by a participating organisation to provide NHS Permission to undertake the study on site.
- f. **Study Start-Deliver:** The start, subsequent delivery and eventual closure of a study at a participating site.
- g. **Study Assurance:** The oversight of a study across all participating sites provided by the sponsor.
- h. **Study Closure:** The activities to conclude a study undertaken by the Chief Investigator and sponsor.

2.8. **Both the participating and sponsoring frameworks include two new areas:**

- a. **The management of a R&D Operational Capability Statement** which is a board-approved statement of agreed R&D operating principles (as part of the organisation's R&D Readiness).
- b. **A rapid and early assessment of operational risks** which may delay or inhibit the decision to give NHS Permission or to sponsor a particular study **using study planning tools (as part of Readiness Assessment).**

2.9. The NIHR SOP dependency frameworks align with the Coordinated System for NHS Permission (CSP) and its implementation using the R&D Management Information System (RDMIS).

2.10. The guidelines are intended to cover the processes associated with typical studies. If a study

is particularly complex or novel because of the nature of the risks then the organisation should seek additional advice and support.

- 2.11. These guidelines are focused on R&D governance SOPs. They are not intended for investigators however they do account for the interfaces between governance processes and investigators, researchers and regulators. They provide an insight of the wider governance processes for these other stakeholders.
- 2.12. The SOP guidelines and the study planning tools are described further in sections 3 and 4.

The R&D Operational Capability Statement

- 2.13. The R&D Operational Capability Statement ('the Statement') is a new document for organisations using the NIHR Research Support Services. It provides information about the organisation's commitment to health R&D and the roles and responsibilities of the different stakeholders in the organisation in delivering these commitments.
- 2.14. The Statement is prepared by the Research Manager, agreed with the other stakeholders such as service managers (for pathology, radiology, pharmacy, etc) **and owned by the organisation's Board.**
- 2.15. The Statement places R&D on the agenda of the board, raising the profile of the R&D office in managing operational risks on behalf of the organisation. It provides a mechanism for:
 - a. reporting of progress (which is increasingly important as part of Quality Accounts reporting),
 - b. escalating any R&D governance decision or issue that cannot be addressed through normal business practice.
- 2.16. The Statement is supported by R&D policies and procedures within the organisation (e.g. 'the organisation will participate in a study provided costs are covered appropriately').
- 2.17. The Statement names key people who are authorised to make decisions on behalf of the organisation, and describes the responsibilities delegated to them. It provides the framework within which the Research Manager is empowered to make governance decisions on behalf of the organisation (when working with investigators, sponsors, etc). It also supports the Research Manager in getting timely support from other stakeholders in making these decisions (such as when progressing NHS Permission for a study or when making a decision to sponsor a study).
- 2.18. **The Statement is particularly important in supporting the early and rapid assessment of operational risks at the start of the NHS Permission process for a new study or when making a sponsoring decision.**
- 2.19. In addition to supporting the Research Manager and R&D office, the Statement contains information which is useful to external stakeholders such as the NIHR CRN and potential sponsors and it is expected that all or part of the content may be shared with these stakeholders.
- 2.20. It is expected that the Statement is reviewed, updated and approved regularly. It is recommended that this is done annually as a minimum.
- 2.21. The content of the Statement should be maintained at a level of detail proportionate to the level and complexity of R&D activity within a particular organisation. For example, organisations that may be planning to be involved as participating organisations in a few lower risk studies over the coming year may have less detail in the Statement than organisations with higher activity involving higher risk studies. It is expected that the level of detail is sufficient to facilitate timely and streamlined R&D governance processes as provided by the NIHR Research Support Services.
- 2.22. The R&D Operational Capability Statement template and management standard operating procedure are described in Annex 3. It is expected that the Statement contains information

on the following areas.

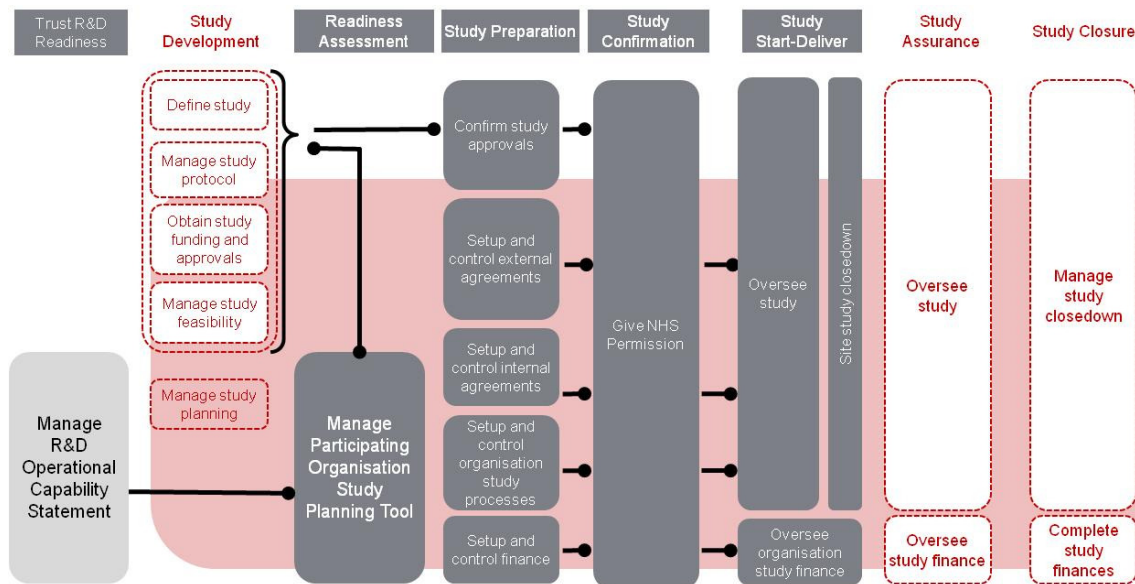
- 2.23. Organisation R&D management arrangements:
 - a. Lead contacts and roles in the R&D office.
 - b. Reporting structures relating to R&D, including role and structure of R&D committees that provide an operational link to clinical services.
 - c. Agreed staffing levels intended to support expected R&D activity.
 - d. Relationships with the NIHR CRN and other networks, including where a network is providing governance services on behalf of the organisation (i.e. where the Board has delegated R&D responsibilities outside of the organisation).
 - e. Collaboration and alliances with other organisations, including where they are providing governance services on behalf of the organisation (i.e. where the Board has delegated R&D responsibilities outside of the organisation).
- 2.24. Organisation study capabilities.
 - a. The types of studies (e.g. CTIMPS phase 3, medical devices, qualitative study, etc) that the organisation is willing and capable of undertaking as a sponsor organisation and / or as a participating organisation and / or as a participant identification centre. These should be matched to the existing or expected capabilities of the organisation to support such studies in the appropriate role.
 - b. Any licences or approvals that the organisation has which support these undertakings.
 - c. For organisations working across primary care it provides information on GP practices.
- 2.25. Organisation services:
 - a. The clinical services that can be provided in supporting studies (e.g. pathology, pharmacy, radiology) and notes on facilities that could be used (e.g. diagnostic services).
 - b. The key contacts within these clinical services who have committed to facilitating R&D decisions quickly.
 - c. Key contacts in management services such as finance, contracts, information, etc who have committed to facilitating R&D decisions quickly.
- 2.26. Organisation R&D Interests:
 - a. The clinical areas in which the organisation is interested and able to support studies.
- 2.27. Organisation R&D planning and investment:
 - a. Agreed plans and funding for R&D developments over the short / medium / long term including training programmes, staff changes, new/updated facilities and equipment, etc.
- 2.28. Organisation R&D SOP register:
 - a. A register of existing approved R&D SOPs within the organisation.
 - b. The processes used for managing Research Passports.
 - c. The agreed escalation process (including escalation to the Board) to be used when R&D governance issues cannot be resolved through normal processes.
- 2.29. Planned and actual studies register:
 - a. Indication of the likely volume of studies that may be undertaken in a given period.
 - b. Reference to a list of studies (may be in a separate database or spreadsheet).
- 2.30. Other information:
 - a. Any other information which may be relevant to the organisation when making R&D governance decisions

3. PARTICIPATING ORGANISATION GUIDELINES

Overview of participating organisation SOPs guidelines

- 3.1. Most NHS organisations will use this set of guidelines when they are intending to host a study sponsored by themselves or (more often) by a commercial or non-commercial sponsor.
- 3.2. Figure 4 shows the areas covered by the SOPs.
- The grey boxes show SOPs used by the participating organisation.
 - The red dotted areas (shown for reference) are the responsibility of the study sponsor / Chief Investigator.
 - The black lines show the key dependencies between the SOPs. Activities in the 'Study Development' and 'Readiness Assessment' and 'Study Preparation' columns can be undertaken in parallel and in particular, study preparation activities should be undertaken in parallel to improve NHS Permission completion times.

Figure 4: The SOP Dependency Framework provides a high-level overview of the R&D life cycle from a participating organisation perspective



3.3. Each grey box in figure 4 represents a SOP guideline summarised in the table below.

Ref	Guideline Title	SOP Overview
B01	Manage R&D Operational Capability Statement	Supports the R&D office in making study readiness and planning decisions based on direction / investment previously agreed by senior management. See Annex 3. The Statement is used by sponsoring and participating organisations.
P02	Manage Participating Organisation Study Planning Tool	Supports the R&D office (with the local investigator) in conducting a quick and early assessment of the operational risks during NHS Permission processes and study delivery for a particular study. This can be used to provide early feedback to the sponsor. Supports the R&D office in preparing a proportionate operational risk management plan.

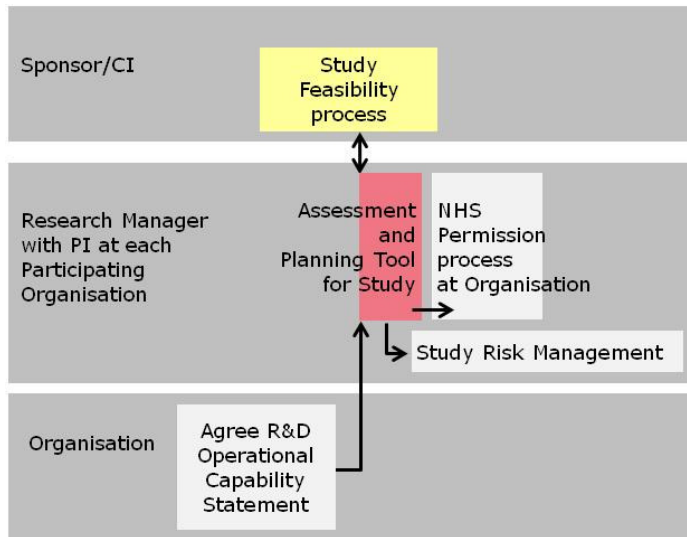
Ref	Guideline Title	SOP Overview
P03	Confirm study approvals	Supports the R&D office in confirming that requisite one-off study-wide approvals have been obtained as part of giving NHS Permission. This is equivalent to accepting 'study wide checks' in CSP.
P04	Setup and control external agreements	Supports the R&D office in completing appropriate study agreements / contracts with other parties (in particular the sponsor) as part of giving NHS Permission.
P05	Setup and control internal agreements	Supports the R&D office in confirming internal agreements with local clinical support services e.g. pharmacy, radiology, pathology etc. to provide services and resources for the study as part of giving NHS Permission.
P06	Setup and control study processes	Supports the R&D office in confirming that appropriate study processes are in place to support the study.
P07	Give NHS Permission	Supports the R&D office in confirming that all approvals, agreements, contracts, financial controls and study processes are in place in order to give NHS Permission.
P08	Oversee study	Supports the R&D office in conducting proportionate governance 'quality control' during delivery of a study (includes audits).
P09	Site study closedown	Supports the R&D office in checking that appropriate activities are completed during study conclusion or earlier termination.
PF1	Setup and control finance	Supports the R&D office in confirming study costs and that appropriate study finance processes are in place.
PF2	Oversee organisation study finance	Supports the R&D office in exercising proportionate oversight of the finances during the study and properly closing down the finances for a study.

- 3.4. Further information is provided for each guideline in **Annex 4**. Further information is provided for the R&D Operational Capability Statement in **Annex 3**.

The Participating Organisation Study Planning Tool

- 3.5. The planning tool is a new tool introduced by the NIHR Research Support Services. **It supports an early and rapid decision-making process conducted at the start of the NHS Permission process.** It enables the Research Manager with the local Principal Investigator to assess any operational risks that may delay the giving of NHS Permission for a study or any impact on the delivery of the study. The planning tool enables the Research Manager to record how the organisation intends to manage these risks. Examples of the organisational risks might include: key individuals who will not be available over the next few weeks, or known issues that will impact on the study e.g. equipment not being available.
- 3.6. The assessment DOES NOT replicate activities undertaken as part of the NHS Permission process, it is a rapid planning tool done as early in the process as possible. It supports the organisation's decision to move from study feasibility to NHS Permission. See figure 5.
- 3.7. The outcome of the assessment is a record of the management actions required to mitigate any potential upcoming risks.
- 3.8. In many sites this quick assessment is done intuitively when information for a new study is received. The planning tool gives a standard structure to this activity.
- 3.9. The assessment is undertaken for each study by the R&D office (or on behalf of the organisation e.g. by a CLRN, as approved in the R&D Operational Capability Statement) with the investigator, and with service managers as needed. It is not intended to be a detailed assessment, but to highlight areas of the NHS Permission process that may need to be addressed earlier or given more attention. The intention is to identify early any potential difficulties or delays allowing the organisation to seek additional support from the sponsor, NIHR CRN or other organisations as required.

Figure 5: Participating Organisation Study Planning Tool



- 3.10. The assessment is based on the risks associated with the study and the capabilities of the organisation to support the study. This means that a high risk study could be addressed by an experienced research site using their existing (NIHR framework-aligned) SOPs, whereas a low risk study at an inexperienced research site may require the site to develop new SOPs and ask for additional support.
- 3.11. An assessment is based on the organisation's capabilities to support a specific study at a specific time. The organisation's capabilities may vary over time for operational reasons such as absences of key staff or non-availability of facilities / equipment required for a study.
- 3.12. The planning tool works best when supported by:
- a. the R&D Operational Capability Statement which provides the framework for making judgements and provides access to the investigator and other key contacts in the organisation to support a timely decision, if required,
 - b. the local investigator and other managers working with the Research Manager in a timely way (these behaviours are reinforced through the R&D Operational Capability Statement),
 - c. the sponsor / Chief Investigator providing the right information (either final versions or good quality draft versions) about the operational needs of the study. The tool can be shared with the sponsor / Chief Investigators to highlight the type of information required.
 - d. the judgement and knowledge of the Research Manager. The tool requires experience to complete quickly.
- 3.13. Use of the study planning tool provides the opportunity to:
- a. create a common start point for the sponsor, investigator, NIHR CRN and the local research governance teams to share information,
 - b. facilitate early engagement with the R&D office and the investigator,
 - c. feed back any governance concerns to the sponsor / Chief Investigator,
 - d. allocate the management of any issues to the appropriate party thereby managing risks that may prevent NHS Permission being given in an appropriate timescale,
 - e. streamline the study feasibility and local NHS Permission processes.
- 3.14. The planning tool and resulting management actions can be revisited if there is a significant change to the study. It can be repeated if necessary to check or re-check risks such as when new information is provided by the sponsor.

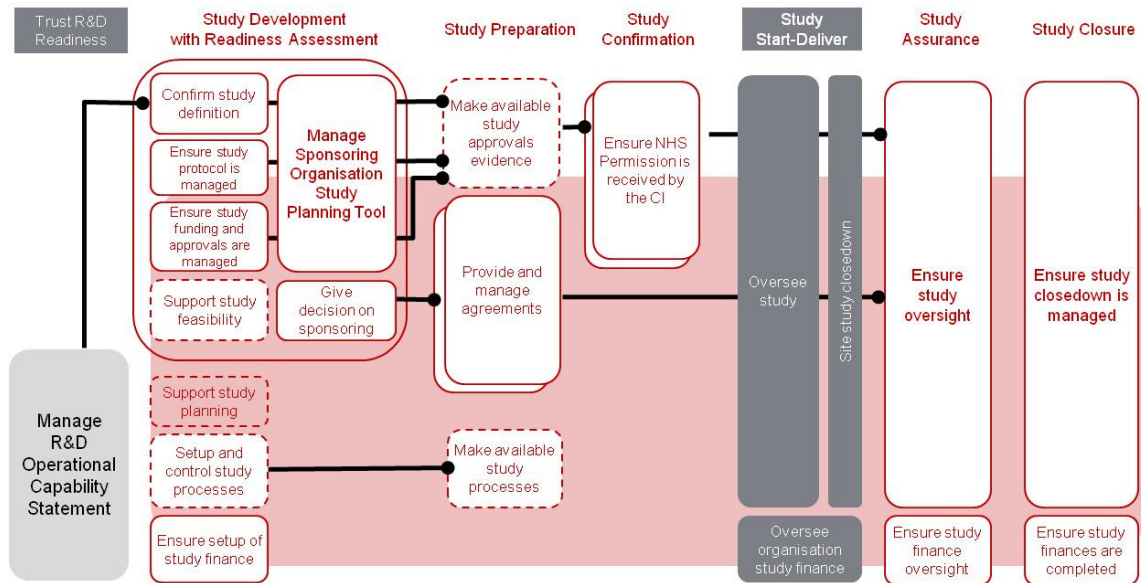
- 3.15. The (one page) Participating Organisation Study Planning Tool is provided in Annex 4 guideline P02. The planning tool covers the following areas:
- a. Study legal and regulatory needs.
 - b. Local alignment (with the R&D Operational Capability Statement).
 - c. Investigator team (support needed during the study).
 - d. Research team (availability for the study).
 - e. Equipment and facilities (availability for the study).
 - f. Supporting services (availability for the study).
 - g. Patient safety (availability of processes and facilities for the study).
 - h. Potential patient population (supporting recruitment).
 - i. Consent (availability of processes and experience for the study).
 - j. Study processes (availability for the study).
 - k. Finance.
 - l. External agreements.
- 3.16. Each area is assessed on the basis of 'Is it likely that the requirements of the study can be met in a timely way?' The more detailed assessments are done during the subsequent NHS Permission process.
- 3.17. The response may be:
- a. yes - using an existing standard process.
 - b. yes - with small (untested) changes to an existing process.
 - c. yes - with significant (but acceptable) changes to an existing process.
 - d. may not be practical to confirm / agree in a reasonable timescale.
- 3.18. These responses require correspondingly more management intervention and provide an indication of the likelihood of giving NHS Permission in an acceptable timescale or of potential issues during delivery of the study. The key output is a short set of proportionate management actions to mitigate any risks during the NHS Permission process or study delivery.

4. SPONSORING ORGANISATION GUIDELINES

Overview of sponsoring organisation SOP guidelines

- 4.1. These guidelines apply when an organisation is sponsoring, or intends to sponsor, a study.
- 4.2. Figure 5 shows the areas covered by these SOPs. The red areas are those SOPs used by the sponsoring organisation. Red dotted areas are the responsibility of the study Chief Investigator and are shown for information and context. The grey boxes are those SOPs used by the participating organisation and are included for reference and context. The lines show the key dependencies between the SOPs. Activities in the ‘Study Development’ and ‘Readiness Assessment’ and ‘Study Preparation’ columns can be undertaken in parallel.

Figure 6: The SOP Dependency Framework provides a high-level overview of the R&D life cycle from a sponsoring organisation perspective



- 4.3. Each red box represents a SOP guideline summarised in the table below.

Ref	Guideline Title	Details
B01	Manage R&D Operational Capability Statement	Supports the R&D office in making study readiness and planning decisions based on direction / investment previously agreed by senior management. See Annex 3. The Statement is used by sponsoring and participating organisations.
S02	Confirm study definition	Supports the R&D office in confirming the study is appropriately categorised and so determines the regulatory framework.
S03	Ensure study protocol is managed	Supports the R&D office in checking that there is an appropriate process for managing the development and amendments of the study protocol including peer review.
S04	Ensure study funding and approvals are managed	Supports the R&D office in checking all necessary study approvals have been obtained and are evidenced.
S05	Manage Sponsoring Organisation Study Planning Tool	Supports the R&D office in conducting a quick and early assessment of the readiness of the organisation to sponsor a particular study. Supports the R&D office in preparing a proportionate risk management plan.
S06	Give decision on sponsoring	Supports the R&D office in determining whether the NHS organisation is able to sponsor a study.

Ref	Guideline Title	Details
S07	Provide and manage agreements	Supports the R&D office in completing appropriate study agreements / contracts with other parties such as participating organisations.
S08	Ensure NHS Permission is received by the CI	Supports the R&D office in checking that a copy of the NHS Permission letter is received by the CI for each participating organisation before the study commences at the site.
S09	Ensure study oversight	Supports the R&D office in to conducting proportionate 'quality control' during delivery of a study.
S10	Ensure study closedown is managed	Supports the R&D office in checking that appropriate activities are completed during study conclusion or earlier termination.
SF1	Ensure setup of study finance	Supports the R&D office in confirming study funding arrangements with the funder(s) and that appropriate study finance management processes are in place.
SF2	Ensure study finance oversight	Supports the R&D office in exercising proportionate oversight of the finances during the study.
SF3	Complete study finances	Supports the R&D office in properly closing down the finances for a study in accordance with current Department of Health and / or NIHR guidance.

4.4. Further information is provided for each guideline in **Annex 5**. Further information is provided for the R&D Operational Capability Statement in **Annex 3**.

The Sponsoring Organisation Study Planning Tool

- 4.5. The sponsoring organisation study planning tool is a new tool introduced by the NIHR Research Support Services. It is an early and rapid assessment conducted for new studies under development which enables the R&D office to understand any operational risks that may influence the decision as to whether to sponsor a study.
- 4.6. The assessment DOES NOT replicate other activities undertaken as part of the R&D approvals process, it is a quick planning tool used as early in the process as possible.
- 4.7. The outcome of the assessment is a set of proportionate management actions required to mitigate any risks in deciding to sponsor a study.
- 4.8. These actions will depend on local circumstances which may change over time as the outcome is based on the organisation's capabilities to support a specific study at a specific time (i.e. an organisation's capabilities may vary over time for operational reasons such as absences of key staff required for a study).
- 4.9. The assessment is undertaken for each study by the R&D office (or on behalf of the organisation e.g. by a CLRN, as approved in the R&D Operational Capability Statement) with support from the investigator as needed. It is not intended to be a detailed assessment, but to highlight areas in the development and approvals processes that may need to be addressed early or given more attention.
- 4.10. The assessment is based on the risks associated with the study and the capabilities of the organisation to support the study. It is therefore feasible that a high risk study could be addressed by an experienced research site using their standard operating procedures, whereas a low risk study at an inexperienced research site may require the site to develop new SOPs and acquire extra support.
- 4.11. The planning tool works best when supported by:
- the R&D Operational Capability Statement which provides the framework for making judgements and access to the appropriate contacts in the organisation to support the decision in a timely way,
 - the investigator and other managers working with the Research Manager (reinforced through the R&D Operational Capability Statement),

- c. the investigator providing the right information (typically good quality draft versions) about the operational needs of the study. The planning tool can be shared with the investigator to highlight the type of information required,
 - d. the judgement and knowledge of the Research Manager to complete the tool quickly.
- 4.12. The planning tool provides the opportunity to:
- a. create a common start point for the investigator and the local research governance teams to share information,
 - b. facilitate early engagement with the R&D office and the investigator,
 - c. feedback any governance concerns to the investigator,
 - d. allocate the management of any issues to the appropriate party thereby managing risks in an appropriate timescale,
 - e. streamline the study approvals and governance processes.
- 4.13. The assessment and resulting management actions can be reviewed when there is a significant change to the study.
- 4.14. The (one page) sponsoring organisation study planning tool is provided in Annex 5 guideline S05. The assessment covers the following areas:
- a. Study legal and regulatory.
 - b. Local alignment (with R&D Operational Capability Statement).
 - c. Investigator team support.
 - d. Research team availability and support.
 - e. Science design (is it likely that sponsor responsibilities can be fulfilled?)
 - f. Patient safety design (is it likely that sponsor responsibilities can be fulfilled?)
 - g. Patient group design (is it likely that sponsor responsibilities can be fulfilled?)
 - h. Feasibility.
 - i. Management and monitoring.
 - j. Confirmation of any split sponsor accountabilities.
 - k. Finance.
 - l. External agreements.
- 4.15. Each area is assessed on the basis 'Is it likely that the requirements of the study can be met in a timely way?' The more detailed assessments are done during the subsequent governance processes.
- 4.16. The response may be:
- a. yes - using an existing standard process.
 - b. yes - with small (untested) changes to an existing process.
 - c. yes - with significant (but acceptable) changes to an existing process.
 - d. may not be practical to confirm / agree in a reasonable timescale.
- 4.17. These responses require correspondingly more management intervention and provide an indication of the likelihood of giving a sponsoring decision in an acceptable timescale or of potential issues during delivery of the study. The key output from this exercise is a short set of proportionate management actions to mitigate the risks.

5. USING THE GUIDELINES

- 5.1. The NIHR expects organisations to:
- a. use and maintain a R&D Operational Capability Statement,
 - b. use the Participating Organisation Study Planning Tool when the organisation is a 'participating organisation'.
 - c. have operating procedures that align with the minimum guidance provided in the NIHR standard operating procedures (SOPs) in this document,
 - d. have a management process in place to review SOPs regularly to reflect any changes in regulations, legislation and good practice. It is expected that this process will allow for both regular review of SOPs and urgent changes. It should address the development, distribution, withdrawal and archiving of SOPs,
- 5.2. NIHR SOP guidelines refer to SOP areas described in the SOP dependency frameworks described in section 2. Guidelines are provided for:
- a. the R&D Operational Capability Statement applicable to all organisations (in Annex 3),
 - b. participating organisations (in Annex 4),
 - c. sponsoring organisations (in Annex 5).
- 5.3. NHS organisations which both sponsor and participate in the same studies need to have versions of both sponsoring and participating organisation SOPs. Some of the participating organisation SOPs can be simplified because they refer to sponsor activities (i.e. the same organisation). This is covered later in this section.
- 5.4. The structure of the SOPs allows for local variations to be incorporated by organisations to suit different local management structures, clinical services, NIHR CRN and local operating models.
- 5.5. The guidelines provide content for use in a standard SOP template. This standard template is provided in Annex 2. It includes:
- 5.6. SOP reference and name
- Each SOP is expected to have a unique reference and clear description.
- 5.7. Version Control
- All changes to SOPs and the currency of SOPs are expected to be recorded.
- 5.8. Purpose and Context
- Provides useful content and rationale to the reader of the SOP.
- 5.9. Procedure
- Provides a table of the tasks within the SOP. The table includes a column to identify who is responsible for the task and a blank column to provide local information on the specific person (role) who is responsible (this may vary between organisations).
 - Additional or more detailed tasks / activities may be added by the organisation provided these are proportionate to the risks associated with specific studies.
 - Organisations may elect to include expected timelines for each task / activity within their SOP.
- 5.10. Supporting material
- This is a placeholder to include additional relevant local information. This could include:

- templates or checklists (specific to the organisation),
- a glossary of terms,
- process flow diagrams and systems user guides,
- links to relevant organisation policy / procedures.

Instructions for using the guidelines

- 5.11. The R&D office should decide which SOPs are required (note that guidelines may contain information on more than one SOP).
- 5.12. For each SOP the R&D office should develop a draft SOP using:
- a. The SOP template.
 - b. Content from section 1 of the guideline (Purpose and context of the SOP).
 - c. Content from section 2 of the guideline (Procedure).
 - d. Content from section 3 of the guideline (Supporting material).
- 5.13. The R&D office should amend the draft SOP to include local requirements. It is expected that SOPs remain consistent with the NIHR guidelines and be developed to apply the principles in a way proportionate to the risks associated with the study. SOPs should take account of the requirements of the specific study, for example the short time windows for initiating a medical devices study, the requirements of ISO 14155 for devices trials and data protection concerns.
- 5.14. The SOP is approved and maintained locally by the organisation.

Using sponsor and participating organisation SOPs in the same organisation

- 5.15. Organisations which are both sponsoring organisations and participating organisations for a particular study need to have versions of both sponsoring and participating organisation SOPs. However, in these cases some of the participating organisation SOPs can be simplified to reflect that sponsoring and participating activity is being undertaken in the same place.
- 5.16. These are examples of changes that can be considered:

Guideline	Possible changes
B01 Manage R&D Operational Capability Statement	A single R&D Operational Capability Statement that covers both sponsoring and participating guidelines.
P02 Manage Participating Organisation Study Planning Tool	This should be done separately as it covers participating site operational risks whereas S05 covers sponsoring risks.
P03 Confirm study approvals	This can be simplified as the organisation itself should have managed the R&D approvals processes.
P04 Setup and control external agreements	This is unlikely to be required as typically the organisation does not have a separate agreement with itself.
P05 Setup and control internal agreements	There is no equivalent sponsor SOP.
P06 Setup and control organisation study processes	This could be simplified as the sponsor prepares some SOPs for studies.
P07 Give NHS Permission	This is done once.
P08 Oversee study	This can be simplified by consolidating study oversight SOPs.
P09 Site study closedown	This can be simplified by consolidating study closedown SOPs.
PF1 Setup and control finance	This can be simplified by consolidating finance setup SOPs.
PF2 Oversee organisation study finance	This can be simplified by consolidating financial oversight SOPs.

List of annexes

5.17. Research Support Services framework annexes

Annex 1 : Glossary of Terms and Acronyms.

As used in the guidelines.

Annex 2 : SOP Template.

Contains the document template for creating a local SOP based on the guidelines. The SOP guidelines use this format.

Annex 3 : R&D Operational Capability Statement.

Contains the SOP guideline for maintaining a R&D Operational Capability Statement

B01 Manage R&D Operational Capability Statement

The Statement template relevant to all NHS organisations.

Annex 4 : Participating Organisation Guideline Documents.

Contains the SOP guidelines for participating organisations:

P02 Manage Participating Organisation Study Planning Tool

P03 Confirm study approvals

P04 Setup and control external agreements

P05 Setup and control internal agreements

P06 Setup and control organisation study processes

P07 Give NHS Permission

P08 Oversee study

P09 Site Study Closedown

PF1 Setup and control finance

PF2 Oversee organisation study finance

Annex 5 : Sponsoring Organisation Guideline Documents.

Contains the SOP guidelines for sponsoring organisations:

S02 Confirm study definition

S03 Ensure study protocol is managed

S04 Ensure study funding and approvals are managed

S05 Manage Sponsoring Organisation Study Planning Tool

S06 Give decision on sponsoring

S07 Provide and manage agreements

S08 Ensure NHS Permission is received by the Chief Investigator

S09 Ensure study oversight

S10 Ensure study closedown is managed

SF1 Ensure setup of study finance

SF2 Ensure study finance oversight

SF3 Ensure study finances are completed

6. NIHR EXPECTATIONS ON THE USE OF THE FRAMEWORK

6.1. The NIHR expects organisations to:

- a. prepare and maintain a R&D Operational Capability Statement agreed by the Board,
- b. use the planning tools to support early and quick risk identification and proportionate risk management,
- c. use existing, updated or new SOPs that are consistent with the NIHR SOP guidelines and which use a proportionate operational risk management approach (i.e. processes are dependent on the level of risk associated with a study and capabilities of the organisation).