NIHR studies

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Version	Date	Reason for Change
Version 1.0	14 Jul 2011	New Procedure
Version 2.0	03 Dec 2012	Annual Review
Version 3.0	18 Feb 2015	Scheduled Review
Version 4.0	25 Oct 2017	Scheduled Review
Version 5.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP. RGIT name change to RGIT.
Version 6.0	29 Oct 2020	Removal of PAF requirement
Version 7.0	03 Nov 2020	Update required to content in the procedure section
Version 8.0	01 Feb 2022	NIHR process updated
Version 9.0	14 Dec 2023	Scheduled Review

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1. PURPOSE

This Standard Operating Procedure (SOP) details what National Institute for Health Research is and how to apply to have a study adopted onto the NIHR portfolio.

2. INTRODUCTION

The goal of the National Institute for Health Research (NIHR) is to create a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public. The NIHR is directed by Professor Lucy Chappell Chief Scientific Adviser for the Department of Health and Social Care (DHSC).

The NIHR brings together government support for research in the NHS in England, through the NIHR Clinical Research Network Coordinating Centre (CRNCC). The NIHR CRN Portfolio is a database of clinical research studies being undertaken in the NHS that are supported by the NIHR Clinical Research Network (CRN) in England.

Details of clinical research studies which meet specific eligibility criteria (see Appendix 1) are recorded in a database known as the UK Clinical Research Network Portfolio, which comprises the NIHR CRN Portfolio in England and the corresponding Portfolios of Northern Ireland, Scotland and Wales.These four Portfolios are held on a single information system: the Central Portfolio Management System (CPMS). The Network has a list of funding partners (see Appendix 2).

Advantages of applying for NIHR adoption include:

- Expert advice on how the study will work in the NHS environment
- Help with site selection
- Review of Organisation Information Document (OID) and a Schedule of Events Cost Attribution Template (SoECAT)
- Access to NHS Service Support.
- Support the delivery in settings such as care homes, hospices, schools, prisons

Imperial policy is that if a study meets the criteria for NIHR Portfolio adoption it should be submitted for adoption.

3. PROCEDURE

3.1. Portfolio Eligibility

Research Studies will only be adopted onto the NIHR Portfolio if they meet the adoption criteria. Studies can be automatically eligible if they have some research funding provided by the NIHR, central government or NIHR non-commercial partner organisations, potentially eligible if initiated by non-commercial investigators with the majority of research being funded by a commercial organisation, funded by overseas Governments or funded by overseas charities. NIHR training schemes may also be considered eligible. To be eligible studies must have met the Definitions for non-commercial studies seeking NIHR CRN support, which includes support to meet NHS Support Costs (or equivalent in non-NHS

settings) Appendix **1 Eligibility Criteria for NIHR Clinical Research Network Support - RGIT_TEMP_044**

3.2. Applying for Portfolio adoption

IRAS form question 5b needs to be selected as yes if study is going to apply for NIHR portfolio adoption. This will ensure key information from the IRAS submission is automatically shared with the NIHR CRN and used to determine eligibility.

If your study is an English-led CTIMP and you are applying for HRA Approval through the HRA and MHRA's combined review service, you must apply for CRN support through the new Non-commercial Portfolio Application service in CPMS. . If the study does not have funding secured by open competition, the Networks will not accept it for adoption.

The following study types can now apply for CRN support via the new service, which allows investigators to apply earlier and receive an eligibility decision sooner to benefit from the full range of support that our study support service offers:

- English-led CTIMP (clinical trials of investigational medicinal products) studies which are led in England and going through the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency's (MHRA) Combined Review Service, and;
- English-led studies that do not need, and therefore are not applying for, HRA Approval in the Integrated Research Application System (IRAS)

Studies that require HRA Approval but are not being progressed through combined review: These studies should continue to apply for NIHR CRN support by selecting **'yes'** to **question 5b** of the IRAS Project Filter. This will ensure key information from your IRAS submission is automatically shared with us. This information, including the IRAS form, the study protocol and grant award letter(s), will be used to determine eligibility. You will be notified of the outcome, via email.

If you are unable to apply via either of these routes, contact your Local CRN for advice on how to proceed.

If you are applying for NIHR CRN support, and have not already done so, you are advised to contact your local Clinical Research Network as soon as possible to access the NIHR CRN's Early Contact and Engagement Service. This is especially important if your study is taking place in a public health or social care setting.

If the Lead R&D site is Imperial College Healthcare NHS Trust (ICHT) then in question A68-2 select North West London CRN as the Local Clinical Research Network.

The full IRAS submission should then be submitted for HRA Approval, as usual. When the submission is deemed valid by HRA (including REC validation if required), Information from the IRAS submission will then automatically be shared with the NIHR CRN and used to determine whether your study is eligible for NIHR CRN support and inclusion on the NIHR CRN Portfolio. The NIHR CRN will notify you of their decision by email.

Please note the IRAS form should only be submitted to the HRA once sponsorship approval has been received from the RGIT.

The HRA will also indicate on their initial assessment letter and approval letter that the study intends to apply for portfolio adoption.

If a study is being considered for the NIHR Clinical Research Network Portfolio, in order to receive service support funding or research infrastructure support through the Comprehensive Clinical Research Network, the Network will email the study team to confirm whether the study is eligible. This **could take up to 30 working days** after the Network receive the IRAS Form and associated documents, including the funding letter. If the Network has any questions a response will be required within **5 working days.**

If the study is considered eligible it will go through the non-commercial adoption process and be added to the portfolio.

3.3. Feasibility Process

Imperial College Healthcare NHS Trust's feasibility process aims to provide support to the study team at an early stage to give the study the best possible chance of successful completion within budget, on time and generating high quality data.

The feasibility of the study will be discussed between the CI/PI/study team and the relevant ICHT Divisional Research Manager (DRM). The final decision on feasibility within ICHT will rest with the DRM. In assessing eligibility a range of criteria will be considered, with the help of other teams around the College and Trust, including evaluations of patient recruitment targets, inclusion/exclusion criteria, equipment and resources, facilities and locations.

Before submitting the study to the HRA the study will need to be sent to the Divisional Research Manager and Feasibility Lead allocated to its specialty. When receiving a study for Imperial sponsorship the RGIT will provide details of the study to the relevant DRM/Feasibility Lead, if it is taking place at ICHT. This will give the DRM/Feasibility Lead the opportunity to raise any issues prior to sponsorship being confirmed. Following HRA approval, DRM confirmation of feasibility must be in place prior to Capacity and Capability (CCC) being issued for ICHT.

Divisional Research Manager and Feasibility Team Leaders contact details can be found in the RGIT_TEMP_009_Divisional-Research-Managers-and-Feasibility-Facilitators.docx

3.4. Capacity and Capability Approval at ICHNT

Studies that are adopted onto the Portfolio follow the same HRA and Capacity and Capability approval process as described in RGIT_SOP_039 Health Research Authority Approval for Research Studies and RGIT_SOP_031 Obtaining ICHT Approval for Healthcare Research.

3.5. Ineligible Studies

If a study is deemed to be ineligible for inclusion onto the Portfolio it cannot proceed through the NIHR system. **This does not affect whether the study can go ahead or not.** Please see RGIT_SOP_031 if your study is deemed ineligible.

When everything is in place a Capacity and Capability (CCC) email will be issued for the study and the project can commence. A copy of the Capacity and Capability email should be placed in the site file and the CI/PI/Study team will have 30 days from the date of approval to recruit its first participant.

3.6. Amendments

Amendments for portfolio-adopted studies follow the same process as described in RGIT_SOP_032 Obtaining ICHT confirmation of continued Capacity and Capability for Amendments to Healthcare Research.

If the RGIT is sponsor to the RGIT Amendments SOP Reference – RGIT_SOP_006

4. MONTHLY REPORTING

If your study is accepted by the NIHR for adoption onto the Portfolio, the study team will have to submit monthly reports on the number of participants recruited to the study.

For more information on how to do this, contact the R&D Office or the study coordinator at the Trust where the study is being conducted. For ICHT contact the relevant Divisional Research Manager.

If the site is within Imperial College Healthcare NHS Trust a recruitment Data Contact needs to be nominated and will require access to Documas or Edge.

Recruitment Data Contact (RDC)

Recruitment data for a study must be uploaded on a monthly basis to Documas or for Cancer Portfolio studies to Edge. The monthly reporting of accurate recruitment data, or indication that there has been no recruitment, is a condition of inclusion of a study in the NIHR CRN Portfolio. A suitable person should be assigned the role of Recruitment Data Contact (RDC) for the study. This person will be responsible for uploading recruitment data for the study on a monthly basis. However, it is still the responsibility of the CI/PI to be accountable for the data upload. Data is centralised via CPMS. Recruitment data is measured against key performance indicators (Higher level objectives) which are used to demonstrate the success of the Clinical Research Network (CRN) and will feed into the process of allocating future funding for NHS infrastructure for research across the Clinical Research Networks. This ensures that infrastructure resources are directed to where they are required for the most patient benefit.

Frequently Asked Questions about recruitment data (Cited 10 Mar 2023)

5. REFERENCES

NIHR (Cited on 10 Mar 2023))

Eligibility for NIHR clinical research network support (Cited on 10 Mar 2023)

Definitions for non-commercial studies seeking NIHR CRN support, which includes support to meet NHS Support Costs (or equivalent in non-NHS settings) (cited on 10 Mar 2023)

NIHR Eligibility FAQS (10 Mar 2023)

NIHR CRN portfolio (Cited on 10 Mar 2023)

NIHR governance (Cited on 10 Mar 2023)

NIHR Learning and support (Cited on 10 Mar 2023)
NIHR performance monitoring (Cited on10 Mar 2023)

NIHR CRN recruitment policy document (Cited on 10 Mar 2023)

IRAS (Integrated Research Application System) updates (Cited on 10 Mar 2023)

NIHR toolkit routemap (Cited on 10 Mar 2023)

Peer Review – RGIT_SOP_040

6. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page.

Appendix 1 Eligibility Criteria for NIHR Clinical Research Network Support - RGIT_TEMP_044
Appendix 2 NIHR Non-Commercial Partner List - RGIT_TEMP_045