

NRS Funding Guidance: Annex 3

Adoption of non-commercial Scottish-only studies – Standard Operating Procedure

A. Introduction

1. Purpose

This Standard Operating Procedure (SOP) describes the process to be used by the NIHR CRN Portfolio Eligibility Team (PET), based within the NIHR CRN National Coordinating Centre, for the adoption of non-commercial Scottish only studies.

2. Background

The NIHR CRN has agreed to provide NHS Research Scotland (NRS) access to the non-commercial adoption process for Scottish only studies not automatically eligible for support through the CSO eligible funders list.

Scotland does not have an adoption process and as such only studies which are funded by an organisation on the CSO list of eligible funders are eligible for the Scottish Portfolio and consequently for support through NRS. From 2012 studies funded by non-eligible funders that are adopted via NIHR CRN non-commercial adoption process will be eligible for support in NRS.

As Scotland is too small to convene independent adoption panels, NIHR agreed to a request that led Scottish only non-commercial studies funded by a non-automatically eligible funder on the CSO list be considered for eligibility through the NIHR CRN non-commercial adoption process.

This SOP describes the process through which the NIHR CRN PET will assess such studies for eligibility.

B. Applicability

This SOP is intended for use by the NIHR CRN Portfolio Eligibility Team, based within the NIHR CRN National Coordinating Centre. This includes the Head of Research Operations, the Non-commercial Research Initiatives Manager, and the Portfolio Eligibility Facilitators and Coordinators.

The SOP has been circulated to Scottish NHS Boards who will be responsible for submitting Scottish studies to the NIHR CRN PET for consideration for adoption.

C. Procedures

1. Application process

1.1 Studies planning to recruit only in Scotland will be forwarded to the NIHR CRN PET (portfolio.applications@nihr.ac.uk) by the leading NHS Board.

1.2 Lead NHS Boards will confirm and forward for review only studies to which the answers to the following two questions are “yes”.

- Has the study had appropriate peer review?
- Was the funding for the study awarded in open national competition?

NIHR CRN PET are not responsible for investigating studies for the above questions.

1.3 All applications for assessment via the NIHR CRN non-commercial adoption process should include the IRAS form, study protocol and grant award letter/contract. In addition the NHS Board should confirm which of the following categories the study is in:

- Funded by overseas Government
- Funded by overseas charity
- Funded by commercial company as collaborative research (or Investigator initiated trial)

1.4 The NIHR CRN PET will take the receipt of an application as confirmation that Scotland wishes to support the study but will not assess whether the study meets the NIHR CRN definition of research.

2. Non-commercial adoption process

2.1 NIHR CRN PET confirm and log receipt of study, review IRAS form and /or protocol.

2.2 The NIHR CRN Portfolio Eligibility Team identify which Specialty is best placed to review the study.

2.3 The NIHR CRN PET send IRAS form, study protocol and standard e-mail to three expert reviewers with request for response within five working days. Expert reviewers asked to complete final two ‘adoption checks’ and complete checklist.

- Is the study of clear value to the NHS?
- Does the study take appropriate account of the priorities, needs and realities of the NHS?

The NIHR CRN PET make the eligibility decision based on the majority view of the experts involved. **NB: Both of the adoption criteria above have to be met for a study to be deemed eligible.**

2.5 The NIHR CRN PET inform the relevant NHS board of the eligibility decision using the standard e-mail template (*detailed in NIHR CRN Portfolio SOP 006 – “the adoption of Scottish Only Studies”*).

Where a not eligible decision is returned the reasons for this decision (taken from the information provided by the expert reviewers) should be included in the standard email.

2.6 NOTE: Responsibility for notifying the study team of the outcome lies with the relevant NHS Board.

2.7 Study teams will be given two weeks (10 working days) in which to appeal a not eligible decision. This appeal will need to be made in writing to the relevant NHS Board addressing the issues raised during the adoption process. If there has been no response from the study team after two weeks then the study should be formally deemed as not eligible. If an appeal is received, the *Appeals process* outlined below will be followed.

3. Appeals process

3.1 Study deemed ineligible at expert review. Study teams given two weeks (10 working days) in which to make a formal appeal in writing. NHS Board sends letter of appeal, addressing the issues raised by the expert review to the NIHR CRN PET.

3.2 NIHR CRN PET acknowledges and logs the appeal.

3.3 NIHR CRN PET sends appeal letter, IRAS form, study protocol and standard e-mail to three additional expert reviewers with request for response within five working days. Expert reviewers asked to complete final two ‘adoption checks’ and complete checklist.

- Is the study of clear value to the NHS?
- Does the study take appropriate account of the priorities, needs and realities of the NHS?

3.4 The NIHR CRN PET collate and review all expert reviewer responses and make the eligibility decision based on the majority view of the experts involved.
NB: Both of the adoption criteria above have to be met for a study to be deemed eligible.

3.5 The NIHR CRN PET inform the relevant NHS Board of the eligibility decision using the standard e-mail template. Where a not eligible decision is returned the reasons for this decision (taken from the information provided by the expert reviewers) should be included in the standard email.

3.6 An appeal can only be made once. The decision following the appeal is final.

Useful links

Eligibility Criteria for NIHR Clinical Research Network Support:

<https://www.nihr.ac.uk/funding-and-support/documents/study-support-service/Eligibility/Eligibility-Criteria-for-NIHR-Clinical-Research-Network-Support.pdf>

Portfolio FAQs

<https://www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support/portfolio-faqs.htm>