

## **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 Team and Network Coordinating Centre Portfolio Teams 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 NRS Scotland and the Scottish Research Networks.

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

As Scotland is too small to convene independent adoption panels, NIHR agreed to a request that Scottish -led non-commercial studies funded by a non-automatically eligible funder be considered for eligibility for NRS Scotland and Scottish Clinical Research Network support through the NIHR CRN non-commercial adoption process.

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

#### **B. Applicability**

This SOP is intended for use by the (NIHR) CRN Portfolio Team. This includes the Portfolio Applications Team, the Portfolio Liaison Manager, the Head of Portfolio Management and other members of the CRN Portfolio Team. It is also intended for use by the Portfolio Teams within the eight NIHR Clinical Research Network Coordinating Centres.

The SOP has been circulated to Scottish NHS Boards in receipt of NRS funding and the Scottish Clinical Research Networks, who will be responsible for submitting Scottish studies to the CRN for consideration for adoption.

## C. Procedures

### 1. Application process

- 1.1 Studies planning to recruit only in Scotland will be forwarded to the CRN Portfolio Application Team ([portfolio.applications@nihr.ac.uk](mailto:portfolio.applications@nihr.ac.uk)) by the participating NHS Board (for single site studies) or the Board carrying out the Generic Management Review (for multi-site studies).
- 1.2 Lead NHS Boards will only forward for review studies to which the answers to the following 2 questions are 'yes'.
  - Has the study had appropriate peer review?
  - Was the funding for the study awarded in open national competition?
- 1.3 All applications for assessment via the NIHR CRN non-commercial adoption process should include the NHS R&D 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 Portfolio Applications Team will take the receipt of an application as confirmation that Scotland wishes to support the study and will not assess whether the study meets the NIHR CRN definition of research

### 2. Non-commercial adoption process

- 2.1 Portfolio Application Team confirm receipt of study, review R&D Form and /or protocol and suggest which network is best placed to manage the adoption process. PAT sends study details (NHS R&D Form, study protocol and grant award letter/ contract) to identified network.
- 2.2 Network confirms that willing to manage adoption process
- 2.3 In accordance with *NIHR CRN Portfolio SOP 002* the network portfolio team identify 3 expert reviewers for the study.
- 2.4 Network Portfolio Team send R&D Form, study protocol and standard e-mail to expert reviewers with request for response within 5 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 network portfolio team 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 network portfolio team inform the relevant NHS Board contact of the eligibility decision using the standard e-mail template (*detailed in NIHR CRN Portfolio SOP 002*).

The PAT is copied into this decision. 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 Study teams will be given 2 weeks (10 working days) in which 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 not response from the study team after 2 weeks then the study should be formally deemed as not eligible. If an appeal is received, the *NIHR CRN eligibility and adoption appeals process* will be followed (see appendix 2 and section 3.).

### 3. Appeals process

- 3.1 Study deemed ineligible at expert review. Study teams given 2 weeks (10 working days) in which to make a formal appeal in writing in accordance with the *NIHR CRN Portfolio SOP 002*. NHS Board sends letter of appeal, addressing the issues raised by the expert review to the Portfolio Application Team.

- 3.2 Portfolio Applications team, logs the appeal in the Scottish only Studies Log and notifies the network that managed the adoption process of the appeal.

- 3.3 Network Portfolio Manager will review the previous decision and the appeal letter and processes the appeal in accordance with the *NIHR CRN Portfolio SOP 002*. Network Portfolio Manager identifies three additional Expert Reviewers to review the appeal and sends appeal letter, R&D Form, study protocol and standard e-mail to expert reviewers with request for response within 5 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 network portfolio team 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 network portfolio team inform the relevant NHS Board contact of the eligibility decision using the standard e-mail template. The PAT is copied into this decision. 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. PAT records appeal decision in Scottish only Studies Log.

- 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, April 2013,**

[http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Portfolio/Documents/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support%20-%20Version%205%20\(April%202013\)%20.pdf](http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Portfolio/Documents/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support%20-%20Version%205%20(April%202013)%20.pdf)

### **Portfolio FAQs**

[www.crncc.nihr.ac.uk/index/clinical/portfolio\\_new/P\\_faqs.html](http://www.crncc.nihr.ac.uk/index/clinical/portfolio_new/P_faqs.html)