NHS Research Scotland

Addition of Scottish led studies to CPMS

V 1.1 29/08/2016

Introduction

This document is intended to provide information on eligibility and recruitment for Scottish led studies and when these studies should be added to the CPMS portfolio.

Please note that information is summarised from several publicly available sources and is not intended as a statement of policy.

NRS follows NIHR guidance on recruitment and eligibility, and reflects the current NRS Funding Guidance.

https://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/faqs/

http://www.nhsresearchscotland.org.uk/working-with-us/researchers/research-funding

For addition to the CPMS portfolio, the following must apply:

- the funder must be deemed as eligible or adopted (outlined in section 1)
- the study must answer the definition of a research question (outlined in section 2)

For recruitment to be uploaded to the CPMS portfolio, the following must apply:

- recruitment must be provided by informed consent (outlined in section 3).

Eligible or adopted studies which answer the definition of a research question but do not obtain informed consent may be added to the CPMS portfolio but must not have recruitment activity uploaded (outlined in section 2).

1. **Assessing the eligibility/adoption status for a Scottish led study**

Eligibility or adoption of a study is determined by the funding stream and assessment of the funder to ensure that research funds are awarded as a result of open competition with high quality peer review.

Research taking place in NHS Scotland and led by Scotland can be deemed as eligible or adopted if it falls within either of the three categories below:

(a) Studies supported by a funder which appear on the CSO eligible funders list have already declared that they provide projects awarded in open competition and are peer reviewed. Funders on this list are deemed as eligible. (See Annex 2 at http://www.nhsresearchscotland.org.uk/working-with-us/researchers/research-funding)

(b) Studies which are supported by a funder which is not on the CSO eligible funders list may apply for adoption if funding is provided by:
- an overseas government *or*
- an overseas charity *or*
- a commercial company as collaborative research

If the funder can confirm that the study was awarded in open competition and has been peer reviewed it may be submitted to NIHR for consideration. (See annex 3 at http://www.nhsresearchscotland.org.uk/working-with-us/researchers/research-funding)

NIHR routinely review studies with English sites, to find out if they are eligible for adoption onto the English NIHR Portfolio. This applies whether or not Scottish sites are involved, and uses the same process as annexe 3. Therefore any English led study with Scottish sites, (or a Scottish led study with English sites) which has been successfully adopted will also be considered eligible in Scotland.

(c) Studies which are led from Scotland and do not meet the criteria above for eligibility or adoption, may be considered eligible in Scotland if there are English sites and NIHR both consider it eligible (see https://www.crn.nihr.ac.uk/wp-content/uploads/Funders%20academics/NIHR%20Partner%20list/NIHR%20Partner%20List.pdf) and are providing support.

(d) All Scottish industry-led studies (where the study has been initiated, funded and sponsored by the company) are eligible for NRS portfolio. Due to concerns over confidentiality, not all Scottish industry-led studies active are added to CPMS. Activity on all Scottish-industry led studies is instead tracked by NRS Commercial Managers within SReDA.

2. Definition of "Research"

Scotland follows NIHR Guidance on the "definition of research study"

https://www.crn.nihr.ac.uk/wp-content/uploads/About%20the%20CRN/Eligibility%20Criteria%20for%20NIHRCRN%20support.pdf

A "research project" is defined as a structured activity which is intended to provide new knowledge which is generalizable (i.e. of value to others in a similar situation) by addressing clearly defined questions.

The establishment or running of a routine tissue bank, a disease registry, data bank, cohort or other resource which underpins a number of research studies, is **not** eligible for addition to the Portfolio.

However, projects where:

- collection and banking of biological samples, inclusion of patient details on a registry, or development of a patient cohort where this activity is **integral to a self-**

contained research project designed to test a clear hypothesis and meets the above definition of research.
or

- where **research projects utilise such resources**

are eligible for addition to CPMS, subject to meeting the other eligibility criteria outlined in section 1. However, uploading of recruitment data to CPMS is **not** appropriate in such cases if they do not also involve informed consent (see criteria for definition of recruitment in section 3).

3. Definition of recruitment

Scotland follows NIHR guidance for recruitment to be uploaded to CPMS:

https://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/faqs/

Specifically, a study participant should be counted if they:

- Have provided informed consent to join a study

and

- count towards the sample size of the study as set out in the study protocol

For cluster randomised trials where entire wards or practices take part without individual consent, then the number of wards/practices should be counted, not the absolute number of patients or participants.

Studies using previously collected samples or data should, as noted in section 2, not report or upload recruitment to CPMS.

4. Addition of Scottish studies to CPMS

NHS Boards are responsible for the addition of eligible or adopted research projects which fulfil the definition of research led from Scotland to the CPMS portfolio.

Responsibility for adding studies to CPMS lies with the R&D office of the NHS Board which hosts the study Chief Investigator.

5. Addition of Recruitment data for Scottish studies to the CPMS Portfolio

Actively recruiting studies on the Portfolio should report recruitment monthly.

NHS boards, acting through the R&D Office are responsible for ensuring the addition of recruitment data for all participating sites, including any in England, Wales or NI.

Actual addition of data will almost always be delegated to the person most able to provide up to date recruitment information, and, in practice, will often be done routinely by a member of the study team. R&D or a Research Network may assist, or take on the role, if necessary, however care should be taken to avoid unnecessary duplication of effort.

For studies which are not led by Scotland, but where Scottish sites are participating and the lead nation is in England, NI or Wales then the lead R&D office in the lead nation will upload Scottish recruitment figures on behalf of Scotland.

In most cases, the site where the patient is consented is included on the recruitment upload, even if this is not an NHS facility. NHS resources required to conduct research in Scotland are allocated on a regional basis, and inclusion of site information enables this.