Scottish studies and the UKCRN Portfolio

NIHR guidance is followed for addition of Scottish studies to the UKCRN portfolio: http://www.crn.nihr.ac.uk/researchers/processes/portfolio/p_eligibility/faqs.

Differences in Scottish structures require slight amendments to approaches to working with the Portfolio, and these are noted below, along with some common questions.

See http://www.cso.scot.nhs.uk/nrs/nrs-funding-2/eligibility-for-nrs-support/ for more information.

1. Definition of eligibility for addition to the UKCRN Portfolio

Research taking place in NHSScotland can be added to the UKCRN Portfolio if it falls into one of the following categories:

(a) Studies supported by a funder which appears on the CSO Eligible Funders list can be added automatically.
(http://www.cso.scot.nhs.uk/wp-content/uploads/2013/05/NRS-Funding-Guidance-Annex-2-Eligible-funders-v4.pdf)

(b) Studies which are supported by a funder which is not on the list may apply for adoption to the Portfolio if funding is provided by:

- an overseas government *or*
- an ineligible national charity *or*
- a commercial concern, but are non-commercially sponsored

The process varies depending on lead site and participating sites:

- Studies led from England with Scottish sites can be considered for adoption by the NIHR CRN
- Scottish-led studies which intend to also recruit in England can be considered for adoption via the NIHR CRN process
- Studies only taking place in Scotland can apply for adoption through the defined process (http://www.cso.scot.nhs.uk/wp-content/uploads/2013/05/NRS-Funding-Guidance-Annex-3-SOP-for-Adoption-v2.1.pdf)

(c) All industry-led studies (where the study has been initiated, funded and sponsored by the company) are eligible for addition to the Scottish Portfolio. Where a study is led from England, this may be carried out by NIHR, however due to

concerns over confidentiality, not all industry-led studies active in Scotland will be added to the Portfolio. Activity on all Scottish-led studies is tracked by NRS Commercial Managers.

If a study does not fall into any of the above categories, it should not be added to the UKCRN Portfolio.

2. Definition of "Research"

Scotland follows NIHR guidance on the definition of "research": (http://www.crn.nihr.ac.uk/researchers/processes/portfolio/p_eligibility/faqs).

A "research project" is defined as a structured activity which is intended to provide new knowledge which is generalisable. Projects must have a clearly defined "research question".

The establishment or running of a 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 form an **integral part of a structured research project** meeting the above definition, *or*
- where **research projects utilise such resources**

are eligible for addition, subject to meeting the other eligibility criteria. However, uploading of recruitment data is **not** appropriate in such cases, and projects should be identified as "sample data only" on the UKCRN Portfolio.

3. Addition of Scottish studies to the UKCRN Portfolio

NHS Boards are responsible for addition of eligible research projects led from Scotland to the UKCRN Portfolio.

The primary contact for addition should be the R&D office of the NHS Board which hosts the study Chief Investigator.

Boards may delegate the actual addition and maintenance of the Portfolio entry to another party, such as a Research Network, but are ultimately responsible if the study has not been added or maintained.

4. Definition of recruitment

Any recruitment to the study should be reported onto the Portfolio. Scotland follows the NIHR guidance:
http://www.crn.nihr.ac.uk/researchers/processes/portfolio/p_recruitment/faqs_recruitment

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 above, not report recruitment, but should be identified on the Portfolio as “Sample data only”

6. Addition of Recruitment data for Scottish studies to the UKCRN 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.

Recruitment for Scottish sites in studies led from England, Wales or NI will be uploaded by the lead site for the study, and should not be entered again by the participating Scottish sites.

In most cases, the postcode of the site where the patient is consented should be included as the recruitment site on the return, 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 postcode information enables this to happen.