NHS SCOTLAND
NHS RESEARCH SCOTLAND

NRS Funding Guidance

This guidance covers the allocation method and data required to inform the Researcher Support and Service Support elements of NRS funding to NHS Boards. It relates to financial allocations for the NHS budget board period April 2020 to March 2021, using data from the reporting period 1 October 2018 to 30 September 2019.

Following the alignment of reporting cycles, information from this exercise will also be used to inform Health Board annual activity reviews.

CSO provides funding to Health Boards to support research activity and maintain a robust infrastructure to facilitate the successful delivery of clinical trials and studies.

Where research activity is marginal, the cost of managing the allocation would be disproportionate and a minimum level of activity is therefore required. CSO will not routinely support a Health Board as part of the fabric of NHS Research Scotland where the total amount of activity would generate funding of less than £150,000.

However, where a health board which is not currently part of the fabric of NHS Research Scotland is involved in the delivery of a clinical trial, CSO will meet Service Support costs as appropriate. A separate arrangement would not be made with the health board in question, rather the board should work through a health board partner, e.g. NHS Highland or NHS Grampian, in order to facilitate the management of the allocation process.

Overall Allocations

The overall allocation will comprise the following:

- NRS Management – contracted separately
- NRS Infrastructure – contracted separately
- NRS Researcher Support – project and recruitment-based elements
- NRS Service Support – activity-based

Contents

NRS Researcher Support

NRS Researcher Support is intended to support the activities of **research active NHS employees** in carrying out eligibly funded research or research adopted to the Scottish Portfolio. As such it will cover:

- time spent on pre-protocol work
- writing applications (both for funding and approvals)
- project coordination and local study management at participating sites of ongoing studies (AcoRD Research Part B activities)
- dissemination (including writing papers)
- general research-related activities such as participating in peer review of other proposals
- time spent on collecting research data (AcoRD Research Part B activity or in other circumstances where low-level activity is not met by the research funder)
- research related admin and clerical support for research active NHS employees.

The budget for Researcher support funding is based on 2 distinct elements:

- Project based
- Recruitment premium

A. Project based element

This will be based on 3 key variables in relation to projects ongoing in the 12-month period 1 October 2018 – 30 September 2019 inclusive.

- is a study single or multi-centre?
- if multi-centre, is the Board in question the lead or host site?
- is the study a CTIMP as defined by the MHRA?

Projects classified as either eligible or extended review (see below for further information) should be included in the return. This data will be generated by the NRS Information & Quality Manager using Health Board data on ReDA. The NRS Information & Quality Manager will quality check each report and submit any data queries to Boards. A final project list will be agreed between the NRS Information & Quality Manager and each Health Board. Details on how the Project List is generated can be found in **Annex 1**.

A project is a defined piece of research directly funded by a research grant. Each project included should have an individual IRAS project number however if a project grant contains research that requires more than one IRAS submission, it should only be included once in the return.

The following points are important to note:

- Where the study is ongoing at more than one location in a Board the return will include a single line for each study, with a column indicating the number of locations. This only applies to Secondary Care locations. Studies ongoing in more than one Primary Care location in the Board will only list 1 location.

- Where a study is funded by more than one funder the return will only include a single line for each study and the first funder listed. The NRS Information & Quality Manager will confirm eligibility status of all studies based on all funders.

- Studies in follow-up, suspended or closed for the duration of the collection period will not be included in the return – this requires Boards to ensure that the field in ReDA that indicates that a study has been closed to recruitment (in follow-up/ Completed/Suspended) and recruitment end date must be up to date at the time of the return.

- Studies where the Board is acting as a Patient Identification Centre (PIC), or where there is No-Local Investigator will not be included.

    - A No-Local Investigator (NLI) study is defined as a study which has no local Health Board PI at any research location within that Board. If a study has multiple locations within the same Health Board which are taking part in a study, operating under the direction of a local Health Board PI, the board PI should be recorded on ReDA at every location. There should normally be at least one CI for each NLI study.

- Studies which are for the collection of tissue/data only **without** any associated research question should not be included; where a study collects tissue/data **and also** answers a research question, it can be included, as can studies utilising previously collected tissue/data.

The following weightings will be applied to studies included in the return to generate proportional funding of the project element of the Researcher Support budget. For studies recruiting at more than one location in a Board, this will be factored into the funding calculation. Additional locations for studies where the board is leading are counted as hosted.

	Non-CTIMP	CTIMP
Single centre	1	2.5
Multi-centre* leading	2	5
Multi-centre* hosting	0.5	1.25

** more than one Board location*

The NRS Information & Quality Manager will submit the agreed project lists to CSO on behalf of Boards. The deadline for provision of this report is **Friday 7th December 2019**.

B. Recruitment Premium

The remainder of the Researcher Support Budget will be allocated in the form of a Recruitment Premium.

Every patient recruited to a commercial or eligible/extended review non-commercial study which meets CSO's definition of a research project (therefore excluding tissue banks and databases) between 1 Oct 2018 and 30 Sept 2019 will be cross-checked by the NRS Information & Quality Manager with the confirmed project returns. Any data which is included in relation to studies where no consent has been obtained (e.g. database studies or those using samples previously collected) will also be excluded from the recruitment premium calculation.

Recruited is defined as the participant provided informed consent to join a study and is taking part in the study (I.e. participants who count towards the sample size of the study as set out in the study protocol and are considered eligible according to any screening tests applicable). Consented participants who have failed post-consent screening should not be included in the return or added to ReDA recruitment tables.

Non-Commercial Recruitment Data

- The NRS Information & Quality Manager will extract the recruitment data from ReDA on **15th November 2019** to allow time for all recruitment to end September to filter through the system into ReDA.
- Boards should ensure that researchers are made aware of the importance of timely uploading of September recruitment to ensure it is counted.
- Boards should ensure and agree the recruitment figures are correct.
- The NRS Information & Quality Manager will provide the recruitment data to each Board, before submitting to the CSO.
- The final ReDA recruitment data cut will be taken on **7th December 2019.** Any recruitment uploaded to ReDA after this date will not be included in the analysis.
- Studies will be stratified based on the policy outlined in **Annex 4.**

Commercial Recruitment Data

- Data will only be counted for studies where the per-patient fee is £1000 or greater Studies where the per-patient fee is less than £1000 will also be recorded but will not be considered as part of allocation calculations.

NRS Service Support

This element of funding will be allocated using an activity-based method, comprising the number of patients recruited to the study and the calculated 'per-patient' cost for that study. The 'per-patient' cost will be either

- For studies submitted for management approval before September 2013:
    - the costs calculated by Boards and advised to CSO (subject to any amendments made by CSO to correct for significant differences between Boards).
- Studies with multiple costs will use the revised single cost per project agreed for the 2016/17 allocations.
- For studies submitted for management approval from September 2013 onwards the 'per-patient' cost calculated by the Lead Board, and recorded onto the NRS Finance System at https://www.nrsfinance.scot.nhs.uk/.

The recruitment data will come from ReDA and is detailed above in Recruitment Premium section.

Eligibility for NRS support

NRS funds can be used to support the following:

1. non-commercial studies funded by a CSO eligible funder (see list in **Annex 2**)

2. studies which are not on the CSO eligible funder list, but which are either led from England, or are led from Scotland with participating English sites, and are considered eligible and supported by the NIHR CRN, either by means of:

    - entry on the NIHR non-commercial partner list: https://www.nihr.ac.uk/documents/nihr-non-commercial-partner-list/11458#3._Current_list_of_NIHR_non-commercial_Partners
    - self-declaration as an NIHR non-commercial partner: https://www.nihr.ac.uk/documents/eligibility-for-nihr-clinical-research-network-support/11604

    Further information can be found here: https://www.nihr.ac.uk/explore-nihr/support/study-support-service.htm

3. Studies which are not on the CSO eligible funder list, but which have successfully applied though the NIHR non-commercial extended review process. This applies to:

    - Investigator initiated trials (i.e. commercial collaborative research)
    - Studies funded by overseas Governments
    - Studies funded by overseas charities

    Further information is provided in **Annex 3.**

4. Studies which are not on the CSO eligible funder list, but are led from either Wales or NI with Scottish sites; or are Scottish-led with sites in NI or Wales, and are considered eligible for support by the devolved administrations in NI and Wales may be also eligible for CSO support, subject to confirmation from CSO.

Projects must meet the CSO definition of research to be supportable – e.g. travel awards, equipment grants, establishment of tissue banks and databases etc. are not eligible.

Studies in the categories above can be included in the Project return for NRS Researcher Support and recruitment will count towards both the Recruitment Premium element of Researcher Support and activity based NRS Service Support. Exceptionally, CSO reserves the right to extend eligibility to particular projects and/or initiatives in relation to particular policy areas.

Chief Scientist Office

September 2019

Annexes

Annexes and electronic versions of this document can be found at the following location:

http://www.nhsresearchscotland.org.uk/education-and-funding/funding-for-nhs-research-infrastructure-2

- Annex 1 – Guidance on the production of the annual project return
- Annex 2 – Eligible funder list
- Annex 3 – Standard operating procedure for adoption of Scotland-only studies
- Annex 4 – Recruitment Premium – Policy on stratification of studies

Further Reference

- CSO guidance on ACoRD is available at:

  http://www.nhsresearchscotland.org.uk/education-and-funding/funding-for-nhs-research-infrastructure-2/acord