NHS SCOTLAND

NHS RESEARCH SCOTLAND

PRIMARY CARE

Guidance for Researchers

Supporting Primary Care Research, Scotland-wide

1. About us

The NRS Primary Care Network ('The Network') facilitates research in primary care. This guide is for researchers who would like to recruit participants from primary care. It focuses on recruitment from GP surgeries, but the Network will assist research in any area of primary care.

The Network is funded by the Chief Scientist Office (CSO) and is coordinated nationally by the network manager and administrator based at the University of Dundee. At a regional level, activity is organised into five 'nodes' based in Aberdeen, Dundee, Edinburgh, Glasgow, and Inverness, covering all health boards in Scotland. The full team listing with local node contacts is on our website.

The Network will support all studies (commercial and non-commercial) that are relevant to primary care, where it is feasible to do so. Studies that have clinically relevant research questions and that place few demands on practice staff tend to be easier to support.

2. Working with the Network

We recommend contacting us in the development phase of a project, and to plan the primary care aspects in liaison with the Network. When a study is brought to us prior to the funding application submission we can provide a letter of support and costing estimate for use in the submission.

We can also assist with studies that are brought to us at a later stage, although adjustments to the protocol and an ethics amendment may be required.

Researchers who would like to use the Network need to complete an 'Application for Support' form. The application can be made at any stage and amended later if required. Projects that will recruit in more than one node will be reviewed by the national team and a 'network study lead' appointed to act as the main point of contact. Applications for projects that will recruit in only one node will be reviewed by the local team.

Once the details of the Network involvement have been agreed these would be documented in a 'Memorandum of Understanding' which both parties would sign.

3. What we can assist with

3.1 Protocol feasibility
3.2 PPI input
3.3 Costing and finance
3.4 Study documentation
3.5 Advertisment and practice recruitment
3.6 Invite patients to participate
3.7 Recruitment of practice staff
3.8 Data collection
3.9 Study completion and dissemination

More information on each of these is given below.

3.1. Protocol Feasibility

It can be very helpful to discuss the protocol with us at an early stage to ensure feasibility in the primary care setting. We will consider:

- The proposed recruitment methods
- Requirements in terms of practice characteristics (health board, deprivation, rurality, list size etc.)
- Whether the patient group can be identified from practice databases
- How many practices and patient invitations may be required to achieve the recruitment target
- What demands the study will place on GP practice staff
- Any likely/possible impacts of the study on practices

If we feel that the proposed methods are not feasible, we will do our best to come up with alternative suggestions.

3.2. Patient and public involvement (PPI) input

Researchers are encouraged to seek PPI for their projects.

The Network can provide access to PPI training for researchers and give advice on PPI costings to include in the funding application. The network has its own PPI group which can assist if required, and researchers who would like this input are encouraged to discuss their project at a Network PPI group meeting. If you would like assistance with PPI please contact our PPI coordinator at nrsprimarycarenetworkadmin@dundee.ac.uk

Resources for researchers wishing to consider how best to involve patients and the public can be found at NHS Research Scotland Help Shape Research.

3.3. Costing and finance

We can provide an estimate of the costs of the primary care elements of the study and manage payments to practices where appropriate.

3.3.1. Service Support Costs

All Network-supported studies must reimburse for the practice staff time required to support the research.

- *Eligibly-Funded Studies*
  For eligibly-funded studies, reimbursement for certain

activities, including checking the patient list, is provided by the CSO 'Support for Science' (SfS) primary care budget, which is managed by the Network.

- *Non-Eligibly Funded Studies*
  Non-eligibly funded studies are not eligible for SfS and the costs must be provided by project funds. In these instances, the costs are treated as Research Costs and will be included in the 'Research Cost Agreement' referred to below.

- *Commercial Studies*
  Commercial studies are not eligible for SfS and all costs must be provided from project funds (discuss with your local commercial R&D manager).

The Network can organise practice reimbursement of costs via BACS transfer for all studies.

3.3.2. Research Costs

Research costs must be provided by the grant or commercial sponsor. Examples of research costs include:

- *Printing and Postage*
  When inviting patients by post, the grant will cover all associated costs. This includes printing, consumables and postage. The researchers will be responsible for calculating and managing these costs. We ask researchers to use the NHS-approved automated service Docmail, or a similar

service, for patient mailings. Network staff are familiar with Docmail and can advise on who to contact for a quote and for account set up. Docmail is a cost and time-effective option, and the current rates can be found on their website.

- *Network mailout admin fee*
  The Network charge a small admin fee to cover the staff time that is required to prepare the mailing. This is classed as a research cost and needs to be reimbursed to the Network. We will provide an estimate for this.

- *Research tasks to be completed by practice staff*
  Some studies require tasks to be carried out by practice staff that are classified as research costs. This includes activities such as the provision of medical histories or participation in interviews. We can provide a list of reimbursement rates to include in project costings.

The Network can facilitate payment of research costs to practices if required and claim these back from the research budget quarterly. Any such costs would be detailed in a 'Research Cost Agreement' to be signed by the researcher and the network representative.

3.3.3. Excess Treatment Costs (ETCs)

ETCs are not required for most studies. ETCs are the difference between the study treatment costs and the costs of the existing standard treatment. In Scotland, all health boards are expected to pay ETCs up to a set limit per study which varies depending

on size of health board. Above this limit it is necessary to apply for a subvention from the CSO. For studies badged as 'primary care,' the ETCs are approved by the CSO via the Network. Other specialties need to discuss these costs with the NHS R&D department in the coordinating health board.

3.4. Study Documentation

Below are some general tips for developing patient and healthcare professional-facing documents. Examples can also be found in the appendices.

If you would like further support with these documents please contact your local node coordinator.

3.4.1. Development of patient-facing documents

General tips:

- **Write clearly and simply and avoid jargon and technical terms**. Documents should be as easy to read as medicine information leaflets or tabloid newspapers.
- Use font size 12pt for the general text and a sans-serif font such as Arial or Calibri.
- Use a lay/short study title in all patient materials.
- Keep the study title, language, and formatting consistent across documents.
- Make the documents attractive and eye-catching if possible.

Documents that may be required:

- *Patient invitation letter*
  This is a letter from the GP to the patient that is printed on the practice letterhead and invites potential participants to consider the study. Ideally it should be no longer than one side of A4. More guidance and an example can be found in Appendix 1.

- *Brief patient information sheet*
  This is recommended for more complex studies. It outlines the study and provides basic information on what participation would involve and is sent with the patient invitation letter. Ideally it should be no more than 2 sides of A4. Folded leaflets can work well. More guidance and an example can be found in Appendix 2.

- *Full patient information sheet*
  This provides all the detail necessary for the patient to make an informed decision regarding participation. Where a brief information sheet is used in the initial approach, the full information sheet is provided by the research team once a patient has expressed an interest.

- *Patient reply slip*
  This is for patients to complete and return to the study team. It enables the team to contact the patient directly. Reply slips are not essential, but it can be useful to include a range of ‘opt-in’ choices for patients. More guidance and an example can be found in Appendix 3.

- *Reply-paid envelope* if a reply slip is used.

3.4.2. Development of healthcare professional-facing documents

General tips:

- Write in a professional-to-professional style.
- Tailor your content to your audience – consider what is of most interest/relevance to GPs

Documents that may be required:

- *GP/Practice invitation letter*
  This is a letter from the research team inviting the practice to consider the study. More guidance and an example can be found in Appendix 4.

- *GP/Practice study summary*
  This outlines the study and provides basic details of what participation would mean for the practice and their patients. More guidance and an example can be found in Appendix 5.

3.5. Advertisement and Practice Recruitment

The Network will begin recruiting GP practices once all approvals are in place (typically Ethics and R&D but others may be required). It is the responsibility of the researcher to provide these to the Network as soon as they are available.

The study will be advertised in the recruiting health boards, almost always by email. Researchers can provide a study advert for the Network to use, or the Network can create one based on the GP

invitation letter. A study advert should be clear and concise. It should let the practice know of any activities they may be required to undertake, any direct or indirect implications of taking part, and any financial reimbursement.

3.6. Patient Identification and Recruitment

GP practices that agree to assist with a study usually invite Network staff to search the practice database on their behalf to identify eligible patients. GPs, or other practice staff as appropriate, would then be asked to review the list of patients to confirm suitability.

Once the patient list has been approved, Network staff will process the patient invitations on behalf of the practice. This is usually done using Docmail. Patients would respond directly to the research team, usually either by completing a reply slip, by phone or weblink. Researchers are then able to get in touch with patients directly using the details patients provide.

3.7. Recruitment of Practice Staff

If a study requires practice staff as participants (e.g., to complete a survey or take part in an interview or focus group) the Network can assist by advertising the study locally or nationally.

3.8. Data Collection

Network staff may be able to collect small amounts of non-identifiable patient data such as SIMD, age and sex. Please discuss any requirements with your Network contact during study set-up and ensure that any planned data collection is explicitly

detailed in the study protocol and ethics application.

3.9. Study Completion and Dissemination

We are very keen to receive a study summary at the end of each project and to hear about any publications of results as we consider it very important to provide feedback to GP practices. We have a twice-yearly ‘Publications Newsletter’ which goes out to all practices in Scotland and gives details of any study publications relating to primary care. GPs have noted it is useful to receive this information.

We will ask you to complete an evaluation form at the end of the study recruitment period which includes information on when you expect to publish, and who it is best to contact for this. You can then expect to be contacted to request this information around the date given if we don’t hear from you first.

4. NIHR Central Portfolio Management System (CPMS)

The CSO require recruitment to all eligibly funded non-commercial studies to be recorded on the NIHR Central Portfolio Management System (CPMS). In Scotland, NRS will be facilitating this using the existing Research Database (ReDA) which will be uploaded to CPMS monthly. Researchers should follow local guidance and respond to any requests for recruitment data.

Researchers should ensure that patients consented in primary care are recorded per GP practice rather than under a secondary care site, and in any other instance where practices act in any capacity above that of a Patient identification Centre (PIC). Additionally, although not required by CSO, the Network would be grateful if researchers could provide the local coordinator with recruitment per GP practice for all studies where it is practicable to do so.

Hyperlinks within this document

1. NRS Primary Care Network website
http://www.nrs.org.uk/primarycare

2. Chief Scientist Office (CSO), Scottish Government Website
http://www.cso.scot.nhs.uk/

3. NRS Primary Care Network Full Team Listing
https://www.nhsresearchscotland.org.uk/research-areas/primary-care/our-staff

4. NRS Primary Care Network Application for Support form
https://www.nhsresearchscotland.org.uk/research-areas/primary-care/study-portfolio

5. Resources for Researchers NHS Research Scotland Website
https://www.nhsresearchscotland.org.uk/public/help-shape-research

6. Eligible funders list, CSO Website
https://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS%20Funding%20Guidance%20-%20Annex%202%20-%20Eligible%20Funders%20Working%20Document%20(4).pdf

7. Docmail website
http://www.docmail.co.uk/

8. Docmail pricing
https://www.docmail.co.uk/prices.html

9. NIHR Central Portfolio Management System (CPMS)
https://cpms.nihr.ac.uk/

Appendix 1 - Patient Invitation Letter

This is guidance on how to compose a patient study invitation letter. A template example is given on the next page.

This is a letter from the GP asking potential participants to consider the study. It must be written from the perspective of the GP, not the research team. It will be sent out from the practice on the practice letterhead.

Keep the invitation letter brief (one side of A4) and do not include any logos. It should include the following:

1. **The name of the study**
   We are letting you know about <<Study description/short or lay title>>

2. **Eligibility**
   State why the patient has been invited in general terms. Try to avoid specific statements about diagnosis. For example, patients may not know they have dementia, or may know their COPD as 'Breathing Problems'.

3. **Who is conducting the research and confidentiality statement?**
   The research is being carried out by <<local team contact name(s)>> (unless no local PI) at <<local hospital/university name>> (unless no local site). Make it explicit that no personal information has been passed on to the researchers.

4. **How to respond to the research team (rather than the practice)**
   If you would like to take part, then please contact the research team by <<give details>>.

<<Practice Letterhead>>

<<Patient Title>> <<Forename>> <<Surname>>
<<Address 1>>
<<Address 2>>
<<Address 3>>
<<Postcode>>

<<Date>>

Dear <<Patient Title>> <<Surname>>,

We are letting you know about the **Blood Pressure Research Study.**

We would like to give you the opportunity to take part in this study. The study is looking at treatments for thickening of the heart wall which can be caused by high blood pressure. If you are not being treated for high blood pressure, please accept our apologies, and ignore this letter.

Dr XXX is running the study from XXX. **We have not passed on your personal details and you do not have to take part.** If you do join the study, you can change your mind at any time.

To find out more about taking part, please read the information sheet enclosed with this letter or contact xxx or xxx (research nurses) on **01234 567 890** for an informal chat.

To take part in the study simply return the reply slip using the FREEPOST envelope provided and one of the research team will contact you. Alternatively, you can contact the research team by phone.

If you have high blood pressure, and are interested in taking part in this study, the researchers would be very pleased to hear from you.

Yours sincerely,

XXX Medical Practice

Appendix 2 - Brief Patient Information Sheet

This is guidance on how to compose a brief patient information sheet. A template example is given on the following page.

The aim of the brief patient information sheets is to provide an interesting outline of the study and encourage the paitent to contact the research team. It should be approximately 2 sides of a4 and include the following:

1. **Header**
   Study logo and short/lay title.

2. **Introductory paragraph**
   Attract the reader's attention by asking a question (or two) related to key eligibility criteria. See below for example questions:

   - Are you interest in a study looking at <<condition>>?
   - Do you have <<insert condition>>?
   - Have you experienced/do you suffer from <<symptom/s>>?

   Include a statement or question to engage the reader, e.g. Would you like to take part in a research study which aims to <<insert information>>.

3. **What is the <<short/lay title>> study about?**
   State the problem and give a short background to the study. State how the study aims to address this problem and why it is important.

4. **Who can take part?**
   Give the key eligibility and exclusion criteria. Bullet points can work well.

5. **What will happen to me if I take part?**
   List the key steps. This may include:

   - Number of study visits
   - Overall timeframe of participant involvement
   - Whether any scans/blood samples or other tests are involved
   - Any interviews/questionnaires
   - Any medication involved.

6. **Do i have to take part in the study?**
   Make it clear that taking part is optional, that a participant can change their mind at any time and that it will not affect their healthcare. By returning the reply slip they are agreeing only to be contacted by the researcher.

7. Who is organising the research?

Include the local team if there is one. If the study is national or international this could also be stated.

8. Who can I contact or more information?

Consider putting contact information in a box to make it stand out. Use the names and job titles of the people likely to make contact (such as research nurses), rather than the CI/PI.

9. Thanks

Thank the potential participant for reading the leaflet.

Blood Pressure Research Study

Have you had high blood pressure?

Have you been taking blood pressure medication for more than two years?

This study may be of interest to you!

What is the Blood Pressure Research Study about?

High blood pressure can cause thickening of the heart wall. This can cause an increased risk of heart attack or stroke. Controlling blood pressure does not always improve this condition. This study will check if you have this heart wall thickening. If you do, you will be invited to take a drug called 'Allopurinol' to see if this treatment improved the heart wall thickening.

Who can take part?

- People aged 40 or over
- People who have been taking blood pressure medication for more than two years.

What wil happen if I take part?

You would be in the sutdy for one year and would:

- continue to take your current medication,
- also take Allopurinol or a placebo (dummy) medication twice a day (you will be randomly assigned to take one or the other)
- attend XXX 8 times for study visits

Visits vary but will include an ultrasound scan, two MRI scans and regular blood tests.

Do I have to take part in the study?

No, it is your choice. If you do decide to take part, you can change your mind at any time. By replying to this invitation, you are agreeing to being contacted by the researchers to discuss the study in more detail. You will then receive the full patient information sheet and be encouraged to ask any questions you may have. You can then decide whether to take part in the study or not. Whatever your decision, your health care will not be affected.

Who is organising and fund the research?

This study is happening across all health board in Scotland. In XXX, the research team is lead by Dr XXX based at XXX. The study is funded by XXX.

For more information you can contact the research nurses - XXX or XXX on 01234 567 890. Alternatively, fill in the reply slip and retun it in the FREEPOST envelope and one of the research team will contact you.

Thank you very much for taking the time to read this leaflet. We would be very pleased to hear from you if you have any questions.

Appendix 3 - Patient Reply Slip

Many researchers include a reply slip with the study invitation. A template example is given on the next page.

A reply-paid envelope needs to provided if using reply slips.

The following should be included:

- Lay/short study title
- Research team contact details, possibly highlighted in a box
- Statement syaing that the patient is happy to be contacted by the research team
- Space for the patient name
- Space for the patient address
- Participant's preferences for how and when to be contacted
- The GP Practice the patient has been invivted from if required.

The patient name and address can be pre-populated if required. Discuss with your network contact.

Blood Pressure Research Study

To take part in the study or to find out more information, please contact the research team by phone or post.

01234 567890

Complete the form below and return this sheet in the FREEPOST envelope.

Yes, I would like to find out more about the study. Please contact me:

Name: ……..

Address: ……..

……..

……..

Daytime phone no: ……..

Evening phone no: ……..

Mobile phone no: ……..

Best time to call: ……..

GP Practice: ……..

Please return the completed form in the enclosed reply-paid envelope.

Thank you!

Appendix 4 - GP Invitation Letter

This is guidance on how to compose the GP invitation letter. A template example is given on the next page.

The GP invitation letter is a letter from the research team to the practice, asking them to consider the study. Keep the letter brief (one side of A4).

- Use a brief, informative, subject line
- Make the first paragraph interesting and clinically relevant - GPs have different priorities from researchers
- Explain why you are writing
- Mention that NRSPCN would facilities their involvement
- Explain what to do next if they are interested in helping.

<<GP Name>>
<<Practice Address>>

Date

Dear <<GP Name>>,

We are letting you now about a research study - the **Blood Pressure Research Study.**

The Blood Pressure Research Study is a drug trial looking at whether taking XXX can improve patient's heart wall thickening, thus in turn reducing the likelihood of heart attack or stroke.

We are writing to ask you and your colleagues if you would like to help with the study. If you took part, on behalf of the practice staff from NRS Primary Care Network would:

Run a search for eligible patients

Invite those patients to the study using the practice letterhead

If you are interested in finding out more about the study and what it would involve for your patients and your practice, please read the information sheet provided.

The research is being carred out by Dr XXX at the XXX.

If your practice would like to take part or to ask any questions, then we would be very pleased to hear from you.

Please contact me directly by phone - Dr XXX on 01234 567 890.

Or contact your local NRS Primary Care Network Coordinator, XXX on XXX@XXX.nhs.scot.

Yours sincerely,

Dr XXX

Appendix 5 - GP Study Summary

This is guidance on how to compose a GP study summary. A template example is given on the next page.

The aim of the document is to encourage the GP practice to make contact about the study. It should be short, written with a progessional audience in mind and should include the following:

1. **Header**
   Study logos and the lay/short little. The full title can also be included.

2. **What the study is about**
   State the probelm, give brief background, and state how the study aims to address the problem/ why it is important.

3. **Key patient eligibility criteria**

4. **What practice involvement would entail**
   List the key steps. This may include:

   - Number of network staff or external research nurse visits
   - Overall timeframe of involvement
   - Whether any blood samples/tests are required
   - Any interviews/questionnaires for practice staff
   - Any prescriptions required from GP and who will pay
   - Any record-keeping or medical history required from GP
   - Any training or contract required of practice staff.

5. **Who is organising and funding the research**
   It is more useful to include details of the local team if there is one. If the study is national or international this could be stated also. State funding source.

6. **What the practice will get out of taking part**
   List any benefits, for example test results, contributing to SIGN or NICE guidelines, financial reimbursement.

7. **Contact for more information**
   This could be the CI/PI and/or Research Nurse.

8. **Thanks**
   Thank the practice staff for reading the leaflet and encourage contact.

Blood Pressure Research Study Summary for GP Practices

What is the Blood Pressure Research Study About?

High blood pressure can cause thickening of the heart wall. This can cause an increased risk of heart attack or stroke. Controlling blood pressure does not always improve this condition. This study will investigate whether Allopurinol can improve heart wall thickening in those patients affected.

Which patients can take part?

- People aged 40 or over
- People who have been taking blood pressure medication for more than two years.

What will happen if the practice takes part?

A member of the NRS Primary Care Network will search the practice database for eligible patients and produce a list for the GP(s) to check. Once the list is checked, the NRS Primary Care Network will send out invitation letters and then 3 weeks later, reminder letters.

Who is organising and funding the research?

This study is happening across all health boards in Scotland. In XXX, the research team are led by Dr XXX based at XXX. The study is funded by XXX.

What will the practice get out of taking part?

The practice will be reimbursed £XX per 100 eligible patients up to a maximum of £XXX. This payment is to cover the GP's time in checking the list of patients.

For more information you can contact the research nurses - XXX or XXX on 01234 567 890.
Alternatively, contact your local NRS Primary Care Network Coordinator
XXX on XXX@XXX.nhs.scot.

Thank you very much for taking the time to read this leaflet. We would be very pleased to hear from your if you have any questions.

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PRIMARY CARE

For full team listing, please visit our website www.nrs.org.uk/primarycare and click on ‘contact us’.

For any general enquiries, please contact our network administrator on NRSPrimaryCareNetworkAdmin@dundee.ac.uk

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