NHS SCOTLAND

NHS RESEARCH SCOTLAND

PRIMARY CARE

Guidance for Researchers

Supporting Primary Care Research, Scotland-wide

1. NRS Primary Care Network

The NRS Primary Care Network facilitates research in primary care. This guide is for any researcher who is considering recruiting participants through primary care. The network can support both commercial and non-commercial studies. This document focuses on recruitment via GP surgeries, but the network will assist research in any area of primary care.

1.1. When should I contact the NRS Primary Care Network?

We strongly recommend that you discuss your study with the network before applying for funding and certainly before submission to the ethics committee. This ensures documents are optimal for recruitment and avoids the need for an amendment later. If, however, your study is already at a later stage (e.g. recruitment extending from a secondary care setting) we are happy to discuss how we might assist and adapt study materials for the primary care setting.

1.1.1. Pre-funding contact

We recommend that the primary care aspects of your protocol be developed in liaison with the network. We invite researchers to contact us early in the study design phase to discuss their proposed recruitment methods. Discussion around recruitment may include:

- How many practices/patients/professionals would be required
- Identifying suitable patients to invite (working within the limits of GP database systems and coding)
- Recruiting primary care professionals (if required)
- Which geographical area(s) you want to recruit from **(see section 1.3)**
- Optimising study documentation (such as invitation letters) for the primary care setting **(see section 4 and appendices)**
- Ensuring ethical approvals include the planned recruitment method and relevant documentation for primary care
- Costs involved, including an estimate of service support costs paid to practices by the NRS Primary Care Network on behalf of Scottish Government Chief Scientist Office **(see section 3.2)**
- Data collection requirements (if any). Please discuss and we'll do our best to help.
- Whether your study requires nurse input (we can advise how best to achieve this as this varies by health board).

Once recruitment methods have been agreed, we can supply a letter of support, which can be submitted along with the funding application.

1.1.2. Funding Secured

Once funding is confirmed and study requirements have been discussed with the NRS Primary Care Network **(see section 1.1.1 above)**, researchers should provide:

- A completed NRS Primary Care Network application for support form
- Ethics approval (if available, but can be supplied later if not)
- R&D approval from each health board that recruitment will take place in (if available, but can be supplied later if not)
- All project documentation (e.g. patient invitation letter) **(see section 4.3).**

Applications for projects that will recruit in more than one node will be reviewed by the network team and your local coordinator will feedback any queries or concerns. Once a recruitment strategy has been agreed, both parties will sign a memorandum of understanding (MOU). We will commence recruitment once copies of the ethics and R&D approval letters have been sent to us and you have provided the patient packs **(see section 4.4).**

1.2. What practical assistance can the NRS Primary Care Network provide?

Network staff will be happy to:

- Assist with protocol development
- Provide costings
- Support the development of study materials
- Contact GP surgeries to ask them to get involved
- Search the practice database for eligible patients based on study criteria
- Ask the GP to check the patient list
- Send out study invitations / reminders to eligible patients
- Collect small amounts of anonymised data (if required).

1.3. Who do I contact?

The NRS Primary Care Network is co-ordinated nationally by the network manager and administrator based in Dundee. At a regional level activity is organised into five 'nodes' based in Aberdeen, Dundee, Edinburgh, Glasgow and Inverness. For our full team listing, please visit our website www.nrs.org.uk/primarycare and click on 'contact us'.

Contact our network administrator on: Tel: 01382 383707
Email: NRSPrimaryCareNetworkAdmin@dundee.ac.uk
or get in touch directly with your local co-ordinator if you are based in Scotland.

2. What kind of studies is it easier to recruit practices to?

The more clinically relevant the question being asked, the more likely practices / professionals are to participate. Studies that look at conditions previously included in the Quality and Outcomes Framework (QOF) are often of interest to GPs and practice managers.

It is easier to recruit practices to studies which place few demands on practice staff time. If your study requires practice staff to carry out additional tasks (e.g. GPs to explain the study and/or take consent) then please discuss this with us, as these can be more challenging.

If your study requires nurse input, we can advise how best to achieve this, for example, using the growing number of practices participating in Research Site Initiative schemes, or using a centralised Clinical Research Facility nurse in areas where these are available.

3. Costs involved in primary care research

Please discuss all costings with your local coordinator in advance of the grant application being submitted where possible.

3.1. Research Costs

All consumables (including postage and envelopes) must be provided from grant funds. Please take into consideration that inviting patients can incur considerable postage costs. For all studies, the NRS Primary Care Network charge a nominal fee to cover staff time for preparing invitation letters. Depending on the requirements of the study there may be other research costs to consider (e.g. providing a medical history, PPI, practice staff taking blood). Ideally, for both commercial and non-commercial studies, research costs should be written into any grant application, although costs will differ. Funding bodies are normally accepting of these recruitment costs in primary care research.

3.2. Service Support Costs

All NRS Primary Care Network-supported studies must reimburse practices for their time and expenses (most commonly GP time for checking the patient list and answering any patient queries). For non-commercial studies, reimbursement for practice staff time is available from the Support for Science budget (provided by the Chief Scientist Office and managed by the network). Commercial studies are required to pay the equivalent as a research cost. Please contact the network manager for a costing if your study is commercially funded. We will organise practice reimbursement via BACS transfer for all studies.

3.3. Treatment Costs

In Scotland, all health boards are expected to pay treatment costs up to a set limit per study (this varies depending on size of health board. Above this limit, it is necessary to apply for a subvention from the Chief Scientist Office, although this is normally granted unless the treatment costs are very large. You should discuss Treatment Cost estimates or payments with the R&D department in the co-ordinating health board.

4. Study materials

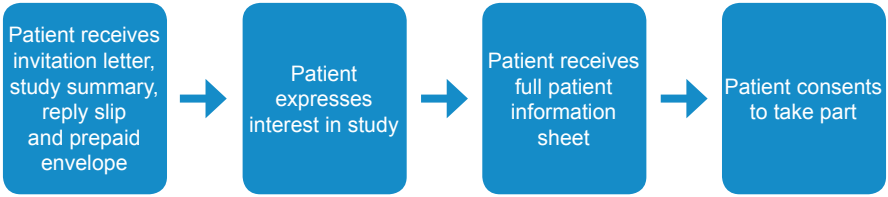
4.1. General advice

Avoid jargon and technical terms, materials should be clear, and as easy to read as medicine information leaflets or tabloid newspapers.

Keep your language consistent across all documentation (study title, document names, formatting, terminology etc).

4.2. Timeline for documents

We recommend that you consider the complexity of the information you are sending and at what stage you are sending it. We strongly advise sending the study summary with the initial invitation, and to follow this with the full patient information sheet once there has been an expression of interest. Please see the timeline overleaf which illustrates this process.



4.3. Documents required by the NRS Primary Care Network

In the appendices you will find information and advice about creating study documents for the primary care setting. Optimising the content and style of patient letters and information sheets **can greatly improve recruitment**, and these templates are based on our positive experience of the effect of well-designed letters and information sheets (and our experience that poorly designed ones usually result in poor recruitment). **Please see the appendices for specific guidance and template examples of each document.**

4.3.1. Participant Documentation

When the NRS Primary Care Network are facilitating recruitment we require the following documentation to be provided by the researchers:

- Patient invitation letter – this is a letter from the GP (on practice letterhead) to potential participants asking them to consider the study **(Appendix 1)**.

- Patient study summary – this outlines the study and provides basic details of what participation would mean for the patient. This is especially useful for complex studies or RCTs. It encourages contact with the researchers **(Appendix 2)**.
- Full Patient information sheet – this provides all study detail necessary for the patient to make an informed decision regarding participation.
- Patient reply slip – this provides contact information for the research team **(Appendix 3)**.
- Reply-paid envelope (if required)

In addition, researchers may want to recruit GPs, dentists or other practice staff as participants in a study. In this case, materials required will be similar to patient documents but with a professional audience in mind.

4.3.2. Professional Documentation

Many researchers provide documentation aimed at GPs in order to encourage them to allow recruitment through their practice. This may include:

- GP invitation letter - this is a letter from the research team, asking the practice to consider the study **(Appendix 4)**.
- GP study summary – this document outlines the study and provides basic details of what participation would mean for the practice **(Appendix 5)**.

4.4. Patient packs and Study IDs

Researchers are required to provide complete packs which contain the patient study summary, reply slip and reply paid envelope. The cover letter is printed in the practice. Please discuss specific details with your local coordinator, but our general requirements are:

- Envelopes must be **window and self-seal** (C4 or C5 depending on what is being sent).
- Envelopes must be **stamped**. Please check that the pack (when it contains all the relevant study documents) is within the thickness / weight allowed by Royal Mail for the postage you have attached.
- We strongly recommend using study IDs if you plan to send reminder letters. Reminder packs must be labelled with study IDs to match the originals. Please speak to your local co-ordinator if you are unsure.
- The patient study ID, if there is one, needs to be easily visible through the envelope window, or written on the outside of the pack. The study packs must be in order if study IDs are used.
- If you expect to be inviting large numbers of patients (100+ per practice), Docmail should be used. Docmail is a secure way of sending mail outs and is more cost effective for larger numbers. The NRS Primary Care Network are familiar with Docmail and can advise on best point of contact for costing and account set up.

5. Patient and public involvement (PPI)

It is strongly encouraged that researchers seek patient / public input into their projects and some funders require it. PPI can help ensure that your research is relevant to those who will ultimately benefit. It can also help to maximise recruitment. It is important to write the methods and costs of PPI into your grant application. 'Involve' provide some useful resources for researchers wishing to consider how best to involve patients and the public.

The NRS Primary Care Network supports innovative ways to involve patients from a diverse range of local communities in primary care research. We can help you to involve patients at any stage of your research. This may be at the stage of setting priorities for research, or in the development of your patient documentation, for example. We can also provide access to PPI training for researchers as well as give advice on PPI costings.

Our PPI group is growing and meet regularly. Our long-term goal is to facilitate patient and public involvement in every research study which we support. Please contact our PPI coordinator Tracy Ibbotson on 0141 330 8309 or email public-patient-involvement@glasgow.ac.uk before you apply for funding, to plan and cost patient involvement into your grant.

6. General Data Protection Regulations

It's important that you explain to people how you will be using their personal data, and what their rights are under the law. This information should be included in the full PIS. The HRA has produced recommended wording to fulfil transparency requirements under the General Data Protection Regulation for health and care research. These wording templates can be found on the HRA website and will vary depending on the type of organisation conducting the research (e.g. NHS, public sector, charity).

7. NIHR Central Portfolio Management System (CPMS)

It is a requirement of the Chief Scientist Office (CSO) that recruitment to all eligibly funded non-commercial studies is recorded on the NIHR Central Portfolio Management System (CPMS). NIHR will be using Local Portfolio Management Systems (LPMS) to record patient recruitment at each study site. Recruitment will be gathered at a local, regional level, using LPMS and uploaded directly to CPMS in real time (overnight). In Scotland, NRS will be using the existing Research Database (ReDA) system as the Scotland–wide LPMS. Information can, however, be uploaded into ReDA from existing electronic systems such as EDGE, CRF Manager. Data from ReDa will be collated and uploaded to CPMS on a monthly basis.
Researchers should, where possible, ensure that patients recruited from primary care are recorded per GP practice rather than under a secondary care site.

Hyperlinks within this document

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

2. NRS Primary Care Network application for support form
http://www.nhsresearchscotland.org.uk/research-areas/primary-care/study-portfolio

3. Quality and Outcomes Framework
http://www.isdscotland.org/Health-Topics/General-Practice/Quality-And-Outcomes-Framework/Clinical-Domain-Points-Available.asp

4. Service Support Costs, NRS Primary Care Network Website
http://www.nhsresearchscotland.org.uk/uploads/files/1447319645PrimaryCareServiceSupportCosts.pdf

5. Docmail
http://www.docmail.co.uk/

6. Resources for Researchers, Involve Website
http://www.invo.org.uk/resource-centre/resource-for-researchers/

7. HRA GDPR guidance template
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/

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

9. Eligible funders list, CSO Website http://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS%20Funding%20Guidance%202018%202019%20-%20Annex%202%20v9%2020.07.18.pdf

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

8. Appendices – Template documents and guidance

The following appendices provide guidance on how to compose your study documentation to make it suitable for the primary care setting. Each page is laid out so that specific guidance relating to the document is detailed on the left-hand side, and a template example of the document is given on the right-hand side.

See below for general guidance which applies to all documentation. **Please get in touch if you would like these templates as a word document so that you can easily adapt for your own study.**

Font
Make sure the font size is 12pt minimum. Use a sans-serif font such as Arial or Calibri. Make sure the study title and any key headings are in a large font.

Colour / images
Try to make the documents as eye-catching as possible (in particular, the patient study summary). Consider using coloured text or background as well as images. A stand-alone cover page works well for the study summary.

Clarity / plain English
Keep the documentation brief (1 side of A4 for a letter, 2 sides of A4 for a study summary). A folded leaflet works well too. Make sure all language is clear, free from jargon and that all complex terminology is explained simply.

Audience
Always consider your audience when composing your document – your writing style should vary depending on whether you are addressing a 'lay' audience or a fellow professional.

Appendix 1 – Patient Invitation letter

This is guidance on how to compose your patient study invitation letter. On the **right-hand side** is a template example.

Remember, the invitation letter **must** be written as coming from the GP, not from the research team, as the letter will be sent out from the practice on the practice letterhead. This is a letter from the GP asking potential participants to consider the study.

Keep the invitation letter brief (one side of A4). It should include the following elements:

1. **The name of the study**
   We are letting you know about … **Bold study description/short title** XXX.
   (Image or logo where appropriate)

2. **Eligibility**
   State why the patient has been invited.

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 XXX.

<<Patient name>>
<<Patient address>>

<<Practice Letterhead>>

Date

Dear <<Patient Name>>,

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 Doolittle is running the study from Edinburgh Royal Infirmary. **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 Jean or Helen (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,

Dr GP

Appendix 2 – Patient Study Summary

This is guidance on how to compose a patient study summary. On the right-hand side is a template example. The aim of the study summary is to encourage the patient to contact you. It should be shorter than the full Participant Information Sheet which will be discussed with the patient by a member of the research team. It should include the following elements:

1. **Header - Insert study logo and a short lay title.**

2. **Key question(s)**
Attract the reader's attention by asking a question (or two) related to your key eligibility criteria. See below for example questions:
   - Are you interested in a study examining… ?
   - Do you have (insert condition)?
   - Have you experienced / do you suffer from… (insert symptom(s)?

Finish with a statement or question to engage the reader. E.g. Would you like to take part in a research study which aims to….

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

4. **Who can take part?**
State the key eligibility and exclusion criteria. Consider only listing the main criteria if there are many, and screen potential participants later. This works best as bullet points.

5. **What will happen if I take part?**
List the key steps. If the protocol is complex, simplify it for the study summary (detail can come in the full PIS). You may want to include:
   - Number of study visits
   - Overall time-frame 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 health-care.
By completing the reply slip, they are agreeing only to be contacted by the researcher.

7. **Who is organising and funding the research?**
It is more useful to put the local team if there is one. If the study is happening nationally / internationally this could be stated also. State funding source.

8. **Who can I contact for more information?**
Consider putting contact information in a box to make it stand out. It is better to put the names and professions of the people likely to make contact, rather than the study PI.

9. **Thanks**
Thank the potential participant for reading the leaflet and encourage contact.

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 improves the heart wall thickening.

Who can take part?
- People aged 40 or over
- being treated for high blood pressure
- blood pressure medication taken for more than two years

What will happen if I take part?
You would be in the study 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 Edinburgh Royal Infirmary 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 funding the research?
This study is happening across all health boards in Scotland. In Lothian, the research team are led by Dr Doolittle based at the Edinburgh Royal Infirmary. The study is funded by the British Heart Foundation.

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British Heart Foundation

For more information you can contact the research nurses – Jean or Helen on 01234 567 890
Alternatively, fill in the reply slip and return 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

Most researchers provide a printed reply slip as part of the study pack. Alternatively, these can be printed along with the invitation letters by network staff if study IDs need to be assigned to keep track of who is responding (for example if you are going to send reminders to non-responders). On the **right-hand side** is a template example.

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

The reply slip needs to be clear on the ways potential participants can contact the research team and should include the following elements:

1. **Bold** study description/short title XXX
2. Research team contact details
3. Form for potential participants to complete
4. Participant's preferences for how and when to be contacted

Please think about your patient group and whether they will be able to complete the reply slip. If this might be a problem, please discuss with your local network co-ordinator as pre-completing the fields may be an option.

Blood Pressure Research Study

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

☎ 01234 567 890

✉ Please complete the form below and return this sheet in the FREEPOST envelope

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Name: ……

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

My contact details:	Best way to contact me (please tick)	Best time to call
Day time number: ……	☐	……
Mobile number: ……	☐	……

Home address:

……

……

……

Appendix 4 – GP invitation letter

This is guidance on how to compose your GP invitation letter. On the **right-hand side** is a template example.

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

- Use a brief, informative, subject line
- Make the first paragraph interesting and relevant - GPs have different priorities from researchers
- Explain why you are writing
- Mention the NRS Primary Care Network
- Explain what to do next if they are interested in taking part.

<<GP name>>
<<Practice address>>

Date

Dear <<GP Name>>,

We are letting you know about a research study – the **Blood Pressure Research Study**

The Blood Pressure Research Study is a drug trial looking at whether taking 'Allopurinol 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 to consider allowing the NRS Primary Care Network to invite eligible patients from your practice to the Blood Pressure Research Study.

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 carried out by Dr Doolittle at the Edinburgh Royal Infirmary.

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 Doolittle on 01234 567 890.

Or contact your local NRS Primary Care Network co-ordinator (insert contact details)

Yours sincerely,

Dr Doolittle

Appendix 5 – GP study summary

This is guidance on how to compose your GP study summary. On the **right-hand side** is a template example.

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

1. **Header - Insert study logos and a short title.**

2. **What is the XXX study about?**
State the problem and a short background to the study.
State how the study aims to address this problem / why it is important

3. **Which patients can take part?**
State the key eligibility and exclusion criteria. Consider only listing the main criteria if there are many. This works best as bullet points.

4. **What will happen if the practice takes part?**
Please discuss the details with your NRS Primary Care Network contact first.
List the key steps. You may want to include:

- Number of network staff or external research nurse visits
- Overall time-frame of involvement
- Whether any blood samples / tests are required of practice staff
- 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 put the local team if there is one. If the study is happening nationally / internationally this could be stated also. State funding source.

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

7. **Who can I contact for more information?**
Consider putting contact information in a box to make it stand out. It is better to put the names and professions of the people likely to make contact, rather than the study PI. Please also add the contact details for the NRS Primary Care Network where possible.

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

Blood Pressure Research Study

Do you have patients with high blood pressure?

This study may be of interest to you…

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
- being treated for high blood pressure
- blood pressure medication taken 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 Lothian, the research team are led by Dr Doolittle based at the Edinburgh Royal Infirmary. The study is funded by the British Heart Foundation.

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What will the practice get out of taking part?
The practice will be reimbursed £80 per 100 eligible patients up to a maximum of £400. This payment is to cover the GP's time in checking the list of eligible patients.

For more information you can contact the research nurses – Jean or Helen on 01234 567 890
Alternatively, contact your local NRS Primary Care Network co-ordinator xxxxx

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.

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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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