



# SPCRN Guidance for Researchers



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## 1. Introduction

The Scottish Primary Care Research Network ([SPCRN](#)<sup>1</sup>) facilitates [eligibly funded](#)<sup>2</sup> research in primary care. We work with researchers to ensure that their study protocols are suitable for the primary care setting, and that the project aims are achievable. We also recruit primary care professionals to research projects, and facilitate the invitation of suitable patients.

This document focuses on research projects based in GP surgeries, but SPCRN will assist research in any area of primary care.

## 2. When to contact SPCRN

We recommend that researchers contact SPCRN early in the design phase of their study to allow discussion of broad issues such as:

- Whether the study question is one that can realistically be answered using the methods proposed
- Whether the study question is relevant to primary care
- Whether primary care is the most appropriate setting
- How many practices/patients/professionals would need to be recruited, and if these figures are realistic
- How patients/participants would be identified
- How patients/participants would be invited to the study
- Funding body to be applied to

If the project is appropriate for SPCRN support we recommend that the primary care aspects of the protocol be developed in liaison with SPCRN.

## 3. Formally applying to SPCRN

Researchers who would like SPCRN to facilitate their study need to formally apply. 'Provisional' or 'full' approval may be sought, depending on whether funding is in place.

### 3.a. Provisional approval

If funding has not yet been secured researchers should apply for provisional approval. Researchers should send their [SPCRN contact](#)<sup>3</sup>:

- A copy of the protocol
- An outline of the relevance of the study to primary care
- Details of the number of practices/patients required

A project that has received provisional approval will receive full approval once funding is in place as long as there are no major changes. SPCRN can supply a letter of support for studies that have received provisional approval, and this can be submitted alongside the grant application.

### 3.b. Full approval

Researchers should apply for full approval if they have secured funding. Researchers should send their [SPCRN contact](#)<sup>4</sup>:

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<sup>1</sup> [www.sspc.ac.uk/spcrn/](http://www.sspc.ac.uk/spcrn/)

<sup>2</sup> <http://www.sspc.ac.uk/spcrn/ELIGIBLE%20FUNDERS.pdf>

<sup>3</sup> <http://www.sspc.ac.uk/spcrn/contacts.htm>

<sup>4</sup> <http://www.sspc.ac.uk/spcrn/contacts.htm>

- A completed [full approval application form](#)<sup>5</sup>
- A copy of the protocol, and ethics application form if available

We strongly recommend that SPCRN is given the opportunity to comment on study materials such as patient and GP literature, as well as the ethics application *before* submission to the ethics committee to avoid delays at a later stage

Once a study is approved both parties will agree and sign a 'memorandum of understanding'. SPCRN will commence recruitment once copies of the ethics and R&D approval letters have been forwarded to us.

#### **4. Reimbursement of primary care professionals/practices**

All SPCRN-supported studies must reimburse practices for their time and expenses. All consumables (including postage) must be provided from grant funds. Reimbursement for practice staff time may be available from the service support budget held by SPCRN. Please discuss this with your local SPCRN coordinator.

#### **5. Projects that may appeal to primary care professionals**

The more clinically relevant the question being asked, the more likely practices/professionals are to participate. Studies that look at conditions included in the QOF ([Quality and Outcomes Framework](#)<sup>6</sup>) are often of interest to GPs and practice managers.

As a general rule, projects should be as simple and undemanding of practice staff time as possible. Studies that require GPs to explain the study to patients and/or take consent are very challenging to recruit to, as are studies that require practice nurse time.

#### **6. Study materials**

##### 6.a. General

- Keep literature as simple and brief as possible
- Consider your audience. Patients are unlikely to understand specialist terminology and GPs have different priorities from researchers.
- Keep your literature consistent. If the cover letter mentions enclosing a study summary, make sure 'study summary' is at the top of the relevant document.
- Some local ethics committees provide model documents such as patient information sheets and consent forms. These are for guidance only and should be adapted as appropriate ([http://www.nhsgrampian.org/nhsgrampian/gra\\_display\\_simple\\_index.jsp?pContentID=3268&p\\_applic=CCC&p\\_service=Content.show&](http://www.nhsgrampian.org/nhsgrampian/gra_display_simple_index.jsp?pContentID=3268&p_applic=CCC&p_service=Content.show&))
- Detailed guidance on study materials is available from the 'Patient Information Sheets and Consent Forms' section of: <http://www.nres.npsa.nhs.uk/applications/guidance/>

##### 6.b. GP/healthcare professional study materials may include:

- GP invitation letter (see [Appendix 1 \[page 7\]](#) for examples)
- GP information sheet and/or study summary
- 'Expression of interest' reply slip and pre-paid envelope if approach is by land-mail
- Copy of patient invitation letter (see [Appendix 2 \[page 9\]](#) for examples)
- Copy of patient information sheet

<sup>5</sup> <http://www.sspc.ac.uk/spcrn/apply.htm>

<sup>6</sup> <http://www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/QOF/index.htm>  
Guidance for Researchers Final.doc 040711

GP/healthcare professional invitation letter tips:

- Keep it brief - ideally no longer than one side of A4. Put the detail into a practitioner information sheet.
- Consider using a brief, informative, subject line
- Make the first paragraph interesting! GPs have different priorities from researchers, so consider how the study question is relevant to the primary care professional.
- Briefly and clearly explain what taking part would involve. If you are collaborating with SPCRn make it clear what SPCRn staff will do on behalf of the practice (discuss with your SPCRn coordinator first).
- Outline what the study would mean for patients
- State what the practice will get out of taking part (test results, contributing to SIGN guidelines, [financial reimbursement](#)<sup>7</sup> etc.)
- Make it easy for practices/GPs to take part. Include a reply slip and reply paid envelope if the approach is by post, and an email address if the approach is electronic. Ensure that contact details are clear.
- Put information such as MREC reference and funding body towards the end of the letter or at the end of the practice information sheet/study summary

### 6.c. Patient materials

In addition to 6.1. above:

- Avoid jargon/technical terms
- Materials should be clear, and ideally as easy to read as medicine information leaflets or tabloid newspapers. The spellchecker on Microsoft Word can be set to display readability statistics.
- Consider the complexity of the information you are sending and at what stage you are sending it. If the study pack is large, consider sending a brief cover letter and simple reply slip initially, to be followed by the full study pack once interest has been expressed.
- Some consent forms can appear complex and may dissuade patients from replying. If the study involves any patient/researcher contact consider asking patients to complete the consent form at this time.

Patient study materials may include:

- Patient invitation letter on GP practice headed paper (see [Appendix 2 \[page 9\]](#) for examples)
- Patient information sheet
- Patient consent form or reply slip, plus pre-paid envelope

## 7. Patient packs

If SPCRn is facilitating the patient invitations researchers are required to provide patient packs that are complete, with the exception of the cover letter. Ready stamped, A4 self-seal window envelopes should be used, unless otherwise agreed with your SPCRn contact.

## 8. Portfolio database

It is a requirement of the [Chief Scientist Office](#)<sup>8</sup> that all [eligibly funded](#)<sup>9</sup> studies be initialised on the [NIHR CRN CC Portfolio Database](#)<sup>10</sup>, and that recruitment figures are updated regularly. It is the researcher's responsibility to do this, although SPCRn can provide guidance if required.

<sup>7</sup> <http://www.sspc.ac.uk/spcrn/apply.htm>

<sup>8</sup> <http://www.cso.scot.nhs.uk/>

<sup>9</sup> <http://www.sspc.ac.uk/spcrn/ELIGIBLE%20FUNDERS.pdf>

<sup>10</sup> <http://www.crnc.nihr.ac.uk/index.html>

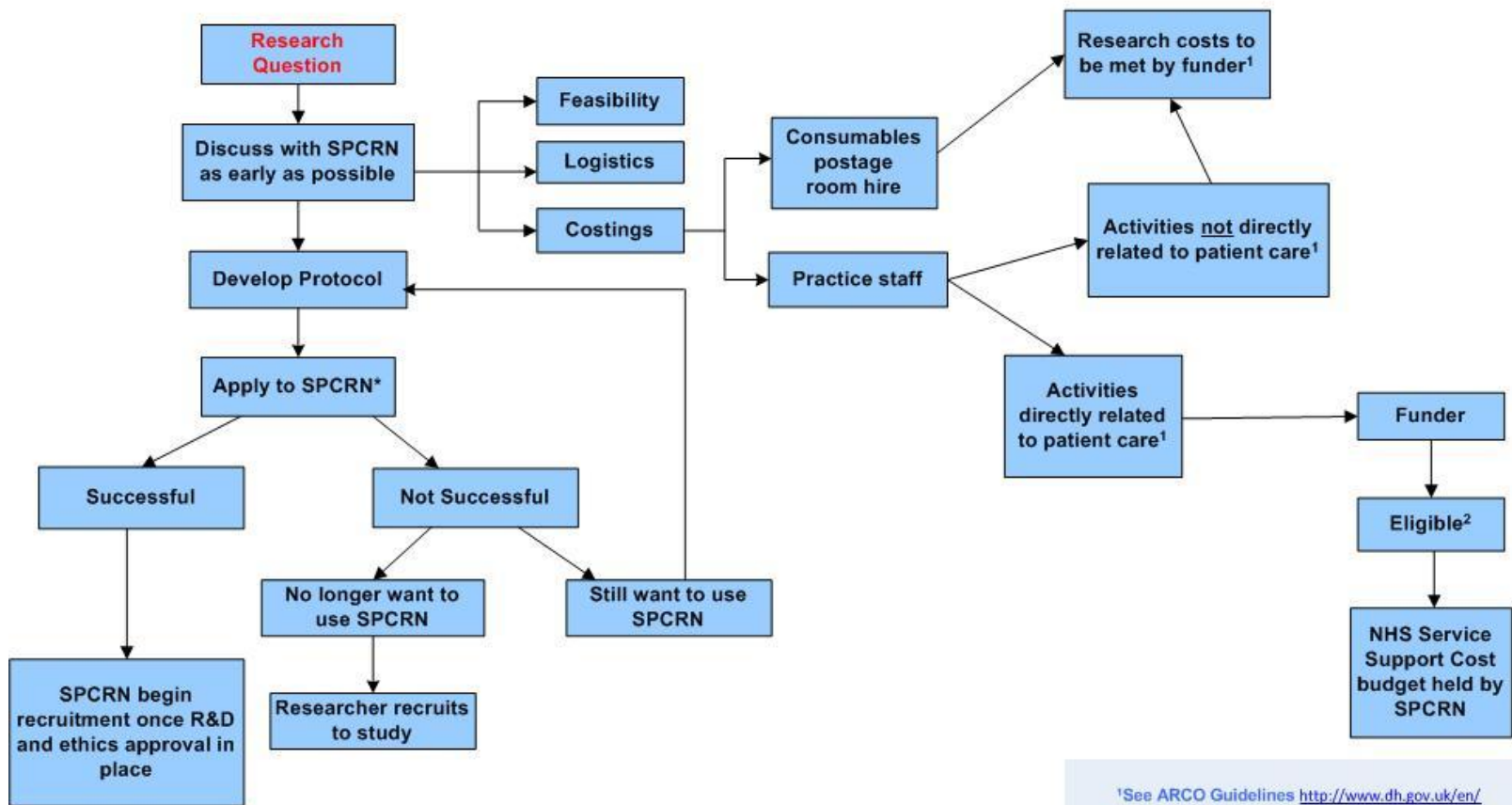
## **9. Patient and public involvement**

It is strongly encouraged that researchers seek patient/public input into their projects wherever possible.

**Good luck with your research!**



### Guidance for Researchers Flowchart



\*Researchers can apply to SPCRN before they have funding, when SPCRN can supply a letter of support which can be used to support the grant application.

¹See ARCO Guidelines [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4125280](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125280)  
²Eligible Funders – see CSO eligible funders list at <http://www.sspc.ac.uk/spcrn/apply.htm>

## APPENDIX 1

### GP Invitation Letter A

Dear Doctor

#### **Pushing forward <<condition>> research**

We are writing to invite your collaboration with this study, which aims to develop primary <<condition>> prevention strategies.

You will know how devastating <<condition>> can be, particularly in younger patients. Our unit is supporting a UK-wide study looking at <<condition>>, the ultimate aim of which is to help to prevent future <<condition>> by identifying predisposing factors.

Our unit is recruiting patients for this study, and we would like to request your assistance. The study is coordinated locally by <<name>> of the <<institution>>.

If you would be willing to assist us, SPCRN would help you to:

- 1) Identify a random list of <<n>> patients who are << broad inclusion/exclusion criteria>>, and
- 2) Send invitation letters to these patients

We would also ask you to screen the list to remove anyone you thought it would be inappropriate for us to approach, if you felt this was necessary.

Patients who agree to take part will be invited to attend <<site>> for collection of a <<sample>> and risk factor profile, and for measurement of <<variable>>. The <<sample>> will be used to test <<factor>> levels, and the results will be passed on to you with the patient's consent.

Our aim is to minimise inconvenience to your Practice, but we need your support for this study to be successful! If you choose to help, your Practice will receive reimbursement of £220 for its time.

Further information on the study is available at <<<http://www.xxx.co.uk/>>>. If you would rather discuss the project in person, please contact <<researcher name>> on <<phone/email>> or your local SPCRN coordinator, <<coordinator name>> on <<phone/email>>.

Many thanks for your time

<<Researcher name>>  
<<Researcher address>>  
<<Researcher tel/email>>

<<SPCRN coordinator name>>  
<<SPCRN coordinator address>>  
<<SPCRN tel/email>>

## **GP Invitation Letter B**

Dear Doctor

### **Incidence, clinical and economic burden of xxx: a prospective observational cohort study in subjects 0-5 years of age**

We are collaborating with <<researchers/funder>> in this Europe-wide epidemiological study, and would like to invite your practice to join the collaboration. <<Condition>> is one of the most frequently reported childhood illnesses, with an estimated x% of severe episodes associated with <<factor>>. The study will measure the overall incidence of <<condition>> as diagnosed by a primary care physician in several European countries. This knowledge will help us understand the public health and economic potential of <<condition>> .

What would be involved for your practice?

1. A list of all patients 0-99 years would be generated. If it would be helpful, SPCRN staff could do this on behalf of the practice
2. A GP would screen the list and remove the names of any that it would be inappropriate to approach for any reason
3. Letters of invitation would be sent on practice headed paper, asking for permission to pass the family's name to the research team. SPCRN staff can help with this. The letter will tell the parents about the study and invite them to indicate whether they are interested in learning more.
4. A research nurse, provided by the university, would collect retrospective data on enrolled patients
5. GPs would be asked to inform the research nurse if any enrolled patients visit the practice with <<condition>>. SPCRN can assist the practice to add an electronic prompt to the practice computer system so that GPs are alerted when an enrolled patient consults.

The average practice will receive reimbursement of £300 for facilitating this study. This amount is based on<<n>> patients recruited and <<n>> completed.

If you would like to take part in this study, or would like more information, please contact either your local SPCRN Co-ordinator, <<coordinator name>> on <<phone/email>> or the lead researcher, <<researcher name>> on <<phone/email>>.

Yours etc

## APPENDIX 2

### Patient Invitation Letter A

#### Practice headed paper

#### Study of <<measurement>> and <<Condition>>

Dear <<patient name>>

We are helping researchers at <<institution>> with a study of how taking <<drug>> can change <<measurement>>.

The researchers need help from patients who are about to start a course of <<drug>> to treat <<condition>>.

Taking part is simple. All you would need to do is give three samples of <<sample>>, one **before** you start taking the treatment, one while you are using the treatment, and one after you have finished the treatment.

Please read the volunteer information sheet in this envelope.

If you would like to help with the study, please telephone the researcher, << researcher name>> on << researcher contact details>>. The researcher will arrange to deliver a sample collection kit to you, and will answer any questions you may have.

A form is included in this pack for you to sign if you are happy to take part in the study. There is also a questionnaire for you to fill in. These forms can be completed before you see <<researcher name>>, or at the time of her visit.

Thank you for thinking about helping with this study.

#### ***The Doctors***

<<Medical Practice>>

## **Patient Invitation Letter B**

### **Practice headed paper**

Dear <<patient name>>

### **Research project looking for new <<factor>> causes of <<condition>>**

We are helping <<institution>> with a research study, and are writing to you to ask if you would be willing to take part. The project is looking at why <<condition>> happens, and needs to compare <<samples>> from people who have <<condition>> with those of people who have not, to see if there are differences. The samples will be used to look for <<factor>> causes of <<condition>>. We hope this will help us understand why <<condition>> occurs, and in the long run it may allow us to develop better treatments.

### **Why have I been asked?**

You have been chosen because you do not have <<condition>>. You are one of a large number of people from the practice that we are asking to help.

### **What would I have to do?**

If you agree to take part, it would involve making a single visit to <<site>> where the study nurse would measure your blood pressure, height and weight, and take a <<sample>>. The nurse would arrange the visit at a time convenient to you, and cover your travel expenses, arranging a taxi if necessary (up to £x each way).

### **How do I reply?**

We would be very grateful if you could complete the reply-slip, telling us whether or not you are interested in taking part. Please post it in the enclosed envelope - no stamp is required. It would help us very much if you can reply even if you do not want to take part so that we know the letter has reached you, and do not trouble you again.

If you are interested in taking part the researchers will send you more details about the study and an appointment. When you go to <<site>> the nurse would answer any questions you have. You would not be under any obligation to take part, and would be free to change your mind at any time.

If you have any questions please contact <<researcher name>>, the study research nurse <<nurse name>>, on <,contact details>>.

Yours sincerely

***The Doctors***

<<Medical Practice>>