

Public Health Research Programme

IMPORTANT INFORMATION & GUIDANCE NOTES - FULL PROPOSALS

Introduction

The Public Health Research programme (PHR) is part of the National Institute for Health Research (NIHR). The secretariat function of the programme is managed by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton under a contract with the Department of Health.

Data Protection

We have an obligation to keep data secure and to use it appropriately. To fulfil our obligations under law and as a result of our contract with the Department of Health, we adopt various procedures to use and protect data. This will impact on how we deal with you as an applicant and your joint applicants. You should bear in mind that we will need to consider data protection issues separately on each occasion that you apply to the programme.

Data Security - data about you

Personal information will be held on a database in the NETSCC password-protected network that is available only to NETSCC staff. Your details and those of your joint applicants will be retained in order to facilitate the running of the PHR programme. If your application is successful at any stage of our process, your name and organisation details will appear on the PHR website. In addition, once funding has been agreed and the contract signed, your details will appear in other PHR literature as a grant holder and will be passed to the Department of Health (DH) for inclusion in their publicly available databases of research projects. Your name and those of your joint applicants will be added to our mailing list. This means that you will be sent updates on the PHR programme. We may also send you separate literature about the PHR programme and related events. If you have any questions, or if you would prefer not to receive routine and/or general communications, please contact us at: info@phr.ac.uk

It is important that you read these guidance notes fully before starting to complete the application form to ensure that you provide the correct information.

Please include items 1,2, & 3 below for primary research, and items 1 & 2 for evidence synthesis:

1. **Electronic Application Form:** Please complete all the relevant sections of the electronic application form.
2. **Detailed Project Description:** Please prepare a detailed project description of your proposed project (as a PDF document).
3. **Flow Diagram (where appropriate):** We recommend you submit a diagram illustrating the study design and flow of participants (as a PDF document).

This document contains information and guidance to assist you with your application and is comprised of four sections:

- **Part One – Information about the PHR programme** (pages 2-5)
- **Part Two – Completing your PHR application form** (pages 5-14)
- **Part Three – Guidance on your Detailed Project Description** (pages 14 -18)
- **Part Four – Submitting your application** (page 19)

Please note that applications which are incorrectly completed may be rejected.

In the letter inviting you to complete a FULL proposal you will have received a link to the full proposal form. Please use this link at all times.

PART 1 – Useful Information for Applicants

Eligibility

The NIHR Public Health Research programme is funded by the NIHR, with contributions from the CSO in Scotland, NISCHR in Wales, and HSC R&D, Public Health Agency, Northern Ireland. Researchers in England, Scotland, Wales and Northern Ireland are eligible to apply for funding under this programme.

Criteria for Assessment

Proposals that have reached this stage have already been assessed by the Programme Advisory Board for public health importance. Full proposals will be assessed by the Research Funding Board on the following criteria:

1. Scientific quality of the proposal:
 - a) What is the likelihood of the study increasing our understanding of the topic area?
 - b) What is the likelihood of the study making a substantial advance in scientific understanding and knowledge?
2. Feasibility of the study:
 - a) Demonstration of the necessary skill mix, experience, project management and infrastructure for success
High quality studies often need a multi-disciplinary team. Applicants need to show a commitment to team working and may wish to consider a collaborative approach between several institutions. Where appropriate, the PHR programme recommends that applicants engage an experienced trial manager for the project.
 - b) Explanation and justification for estimated recruitment rates.
The PHR programme wants studies to achieve their aims. Researchers should demonstrate that they can recruit the necessary number of participants.

- c) Consideration of the ethical, legal and social implications of the research proposed.

3. Reasonable costs and value for money.

There are no fixed limits on the duration of projects or funding and proposals should be tailored to fully address the problem.

Required Expertise

Public health evaluations are typically multi-disciplinary enterprises and are likely to draw on varying areas of expertise. The PHR programme recommends that teams proposing randomised controlled trials include input from an experienced trials unit. A commitment to team working is encouraged and applicants may wish to consider a collaborative approach between several institutions.

Partner Collaborations

The PHR programme expects that applicants will collaborate, where appropriate, with partner organisations, such as local government and voluntary organisations.

Governance and Regulation

The PHR programme expects applicants to follow ethical guidelines appropriate to the study and setting proposed. We will scrutinise proposed ethics arrangements as part of the assessment of applications. Applicants must either comply with the research ethics framework formulated by the Economic and Social Research Council (ESRC) or obtain approval via the National Research Ethics Service (NRES).

Ethics

The Social Care REC reviews adult social care research study proposals from researchers based in England. It is part of the [National Research Ethics Service \(NRES\)](#), and its membership, expertise and procedures have been developed to reflect the social care context. The Appointing Authority is the Social Care Institute for Excellence (SCIE) and the REC is funded by the Department of Health.

The remit of an NHS REC

Ethical advice from the appropriate NHS REC is required for any research proposal involving:

1. Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions
2. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above
3. access to data, organs or other bodily material of past and present NHS patients
4. foetal material and IVF involving NHS patients
5. the recently dead in NHS premises
6. the use of, or potential access to, NHS premises or facilities
7. NHS staff - recruited as research participants by virtue of their professional role."

The Governance Arrangements for Research Ethics Committees (GAfREC) allows for ethical review of research outside the NHS on a voluntary basis:

If requested to do so, an NHS REC may also provide an opinion on the ethics of similar research studies not involving the categories listed above, carried out for example by private sector companies, the Medical Research Council (or other public sector organisations), charities or universities."

In addition to the requirements set out in GAfREC, if your study will take place in a prison or a young offender institution in England and Wales and is health related, it requires ethical review by a NHS REC under an agreement between the Department of Health and the National Offender Management Service.

Ethical approval need not be sought prior to application but details of how ethical approval will be obtained should be included as part of the application.

Useful links:

- Department of Health's Research Governance Framework for Health and Social Care - http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962
- ESRC Research Ethics Framework - <http://www.esrc.ac.uk/ESRCInfoCentre/opportunities/research%5Fethics%5Fframework/>
- National Research Ethics Service - <http://www.nres.npsa.nhs.uk/>.
- Medical Research Council's GCP guidelines - (www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416) in planning how studies, particularly RCTs, will be supervised.
- The Department of Health/MRC website (www.ct-toolkit.ac.uk/) also contains the latest information about Clinical Trials regulations and a helpful FAQ page.

Public Involvement

Public involvement is important and will be actively sought across the PHR programme. Evidence of public involvement will be sought in applications, and comments from reviewers who are members of the public will be regularly obtained.

The PHR programme recognises the increasing active involvement of members of the public in research and would like to support research projects appropriately. The PHR programme encourages applicants to consider *how* the scientific quality, feasibility or practicality of their proposal might be improved by involving members of the public.

Research teams wishing to involve members of the public should include in their application:

- the aims of active involvement in this project;
- a description of the members of the public (to be) involved;
- a description of the methods of involvement;
- and an appropriate budget.

Applications that involve members of the public will not, for that reason alone, be favoured over proposals that do not, but it is hoped that the involvement of members of the public will improve the quality of the application.

One useful resource is:

INVOLVE (www.invo.org.uk/) is a National Advisory Group funded by the Department of Health, which aims to promote active public involvement in NHS, public health and social care research. INVOLVE have published a number of documents aimed at researchers seeking to involve the public in their research including:

- [Involving the public in NHS, public health, and social care research: Briefing Notes for Researchers](#)
- [Suggested guidance for grant applicants about involving the public in research](#)
- [A guide to reimbursing and paying members of the public who are actively involved in research: For researchers and research commissioners, \(who may also be people who use services\)](#)

INVOLVE also produce a useful web page aimed at members of the public wishing to get actively involved in research (other than as a trial participant) [Getting Involved in Research - a Guide for Consumers](#).

PART 2 – Submitting a Full Proposal

General Information

To submit a full proposal you must complete all the pages of the electronic application full proposal form and, if appropriate to your study, for example if an RCT is proposed, we recommend you provide a flow diagram as this will help the programme understand the design of your study. (This should be a single side of A4 as a .pdf file, please include the project title as a heading for the flow diagram).

Please note that the only documents that will be accepted and considered by the PHR programme are the full application form, the detailed project description and, where appropriate, the flow diagram. Any other documents submitted will be removed and not considered in the assessment process, the only exception to this are letters from collaborators relating to payment of intervention costs, please see section H below.

On-screen help is provided by the 'Assistant', shown as a ? mark on screen, and you should refer to this for guidance on specific questions as you complete your application form.

Saving your form

It is advisable to save your form soon after you begin. To do this, click the *Save* button, making sure that you take note of your *Save ID*, located in the top right hand corner of the screen. This is the ID number for your application and will be sent to you via email, to the email address that you provide when you first save the form. The email will include a direct URL link to access your form.

Giving others access to the form

If you send a colleague the *Save ID* for the form they can access and make changes to your form, however only one person can access the form at any one time.

Exiting your form correctly

Should you wish to exit and return to the form at any time, the Save ID will be required to re-access the form.

Please note that you must click the 'EXIT' button on the screen before closing the window that contains the application rather than closing down your internet browser. This will ensure that you are not temporarily locked out of your form.

Locked form

If you are locked out of the form an on-screen notice will let you know how many minutes remain before the form is unlocked.

If a colleague is currently using the form you will need to wait until they have exited the form, as only one person can access it at any one time.

If you are sure that no-one else is using the form, but are still locked out, then please try the following before calling the PHR office for assistance:

1. Wait for the lock-out time to expire
2. Re-boot your computer completely, as sometimes a hidden copy of the form is created in the background
3. Instead of clicking on the weblink in your letter or email, copy the link and paste it into a new internet browser window

Space restrictions when entering text

You should be aware that there are character limits set for each text box within the application form; this is to ensure that the form can print out correctly and limits depend on the amount of text inserted into each box.

We advise you to type your information directly into the form rather than cutting and pasting it. However, if you do cut and paste text into the form and exceed the character limit, an error message will appear. This states *'There is too much text to fit on printed form. It has been changed to indicate where the limit has been reached'*. A symbol '<----->' will appear within the body of text inserted to indicate the character limit for the text box.

The form counts all blank space as a part of the content of each box, so if you are short of space it will help if you delete extra carriage returns and place any bulleted lists into paragraph format. Please take particular care when removing excess text below the < ----- > symbol that you also remove carriage returns, otherwise the application alert will still note that you have too much text in the field.

Use of non-standard characters

You are advised not to use any non-standard characters in your text; in particular, you may experience a technical difficulty that affects the use of '≥' and '≤'.

If you use either of these symbols you will get an error message; if you need to use either '≤' or '≥' then please replace these symbols with words (i.e. less than or equal to or greater than or equal to). You will not be able to submit the form if you have either of these symbols or any other non-alphabetical or non-numerical characters in your text.

Completing Your Electronic Application Form

Research Type

Please indicate whether the proposed study is primary research or evidence synthesis. If there are any elements of primary research, please select 'primary research'.

Section A: Details of Lead Applicant

Please complete all sections and state the contribution towards the proposed project (e.g. lead applicant, principal investigator, data collection, co-ordination and project management, analysis, methodological input, consumer input). Please note that all correspondence will be addressed to the lead applicant. The lead applicant is responsible for communicating decisions from the PHR programme to members of the project team.

Section B: Project Details

Start Date: Please be realistic about your possible start date taking account of the necessary contracting and recruitment time that you may need prior to starting your project.

Research Grant applied for: Research costs are the costs of the research activity itself. These include data collection, analysis, other activities needed to answer the research questions, trial registration (if required) and the salary and indirect costs of staff employed to carry out the research. It is in applicants' interests to undertake a thorough, realistic and accurate costing. This box will be automatically completed from the totals in section M2 of the application form. The PHR programme expects that costs identified should not differ between outline and full proposal stage. The Board will pay close scrutiny to increases and applicants must provide a clear and full justification for any differences.

<p>Please <u>do not</u> include intervention costs in this section. The Public Health Research programme will fund research costs but not intervention or other non-research costs.</p>
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Section C: Project Details & Justification

C1 Researcher-led call – What is the main research question?

Please list the main research question that your proposal seeks to address in question format. You should also include a clear explanation of research question.

or

C1 Commissioned call - How is this proposal relevant to the Commissioning Brief

Please provide a statement explaining how the proposed research project will address the research question posed in the commissioning brief.

C2 Describe the intervention being evaluated.

Please provide the information requested about the intervention: what it is, the setting in which it will be delivered, who will deliver it and who will provide funding. If there are any

NHS components (including funding and organisational support) within your proposal, please clearly characterise them. Give a brief explanation of the methods proposed.

C3 For the main research question, please state:

(1) the participants

(2) the comparator (if relevant)

(3) the outcomes

Please ensure that your proposal has clearly described health outcomes which support the remit of the PHR programme - *The programme evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme is multi-disciplinary and broad.*

C4 Are there any other questions the research project aims to answer?

Please state any subsidiary questions your project seeks to answer.

C5 Please state why the research questions are important now for improving the health of the public, and will they address inequalities in health? (Please note this question is not applicable if you are responding to a PHR Commissioning Brief).

Please provide a clear explanation of the problem to be addressed and why it is important to public health. You should include an explanation of how the research results will be used in your response. Give reference to any relevant systematic review(s) and discuss the need for your study in the light of the(se) review(s). If you believe that no relevant previous studies have been done, give details of your search strategy for existing studies. Please give details of other studies currently underway, both nationally and internationally, which are relevant to the proposed study. Please explain why this research is needed now.

C6 Summary for the non-expert

Please provide a summary of Sections C1-C5. The summary should enable the non-expert reviewer to understand the following: how the proposal addresses the research proposed, how and where the research will be carried out, what outcomes will be used to assess the success of the research, what (if any) are the ethical issues involved in this study and the arrangements for handling these, why this team is well placed to carry out the research, and provide a justification for the costs requested.

More detail on writing for public consumption is available from the Plain English Campaign. A free guide designed specifically for the Health Sector can be found at:

www.plainenglish.co.uk/medicalguide.pdf.

Section D: Summary of Project

The Research Funding Board requires a clear and succinct summary of your proposed research. Please use the following headings as appropriate.

For primary research proposals:

- *Design*: Give a brief statement on the type of study design to be used
- *Setting*: State the setting(s) in which the study will occur
- *Target population*: Define the population from which the study sample will be recruited (e.g. women over 60, people with learning disability, deprived urban communities)
- *Intervention being evaluated*: Give a clear definition of the intervention to be evaluated and include a rough estimate of its cost.
- *Measurement of outcomes and duration of follow up*: Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives, the proposed duration of the intervention and frequency and duration of follow up. Validated surrogate markers are acceptable, where appropriate
- *Sample size*: State the required sample size, giving details of the estimated effect size, power and/or precision employed in the calculation. A full justification of the estimated effect size must be provided
- *Planned analyses*: Please give details of the planned analyses
- *Project timetables including, where appropriate, recruitment rate*: Indicate the anticipated duration of the study, paying particular attention to the expected recruitment rate and a justification for your estimate. Outline the main stages of the proposed project with expected durations.

For Evidence Synthesis proposals:

- *Methods*: Give a brief statement of the methods to be used
- *Target population and setting*: Specify the population from the original studies to be included.
- *Intervention being evaluated*: Give a clear definition of the intervention to be evaluated and, where possible, include a rough estimate of its cost.
- *Search strategy*: Provide details of the body of existing evidence that will be covered and access arrangements (e.g. use of databases, hand-searching, communication with authors).
- *Review Process*: Explain the criteria applied to assess the quality and relevance of studies identified by the search strategy. Provide an explanation of how these will be decided if these are not yet known.
- *Expected output of research*: Outline how report conclusions will be presented: synthesis type (qualitative / quantitative) and recommendations for further research.
- *Project timetables*: indicate the anticipated duration of the study. Outline the main stages of the proposed project with expected durations.

Section E: Team Expertise

Outline the particular contribution each member of the team will make towards the project. The team should be multidisciplinary and include all relevant expertise to enable delivery of the proposed research. The PHR programme suggests teams proposing randomised controlled trials to include input from an experienced trials unit.

The PHR Board welcomes information on you or your team's wider research activities. We are particularly keen to hear about how your previous or current work will fit with this application.

Section F: Details of Joint Applicants

You must complete personal details of everyone involved and state their contribution towards the proposed project (e.g. data collection, coordination and project management, analysis, methodological input, service user input).

In exceptional circumstances there may be more than 24 co-applicants in which case you should create a second supplementary electronic application form and use it in the same way as you did the first one.

Do not include collaborators (individuals who will contribute to the research but do not have responsibility for its management) in this section. Collaborators should be included under 'Expertise' in section 14 of your Detailed Project Description.

Section G: Curriculum vitae of co-applicants.

If you have more than twenty-four joint applicants, you should create an extra file as explained above, and include complete CV details as requested in Section C3. If you have service user applicants, please note that not all sections of the curriculum vitae apply and you should complete as appropriate.

Section H: Partner Collaboration

H1 The PHR Board expects that applicants will work, where appropriate, with the relevant partnership organisations, for example local authorities or charities. Please state which partner organisations you intend to work with.

H2 Please specify what role any partners will have, and indicate the level of progress in developing the collaboration. Please supply as much detail as you can.

H3 If you are proposing a study which requires joint or shared funding, please provide a clear explanation of the arrangements for this. Please explain what costs e.g. intervention costs, relating to your proposed study will be met by your collaborating partners. If you have evidence of these arrangements e.g. letters of support please include these with your application.

Section I: Other Key Information

I1 Please note that the PHR programme will not accept applications that are currently pending with other research funding organisations (unless under shared funding arrangements).

I2 Please provide full details on any patents (or other exploitable results) that may arise from the research.

I3 Please declare any interests that you or any of your other applicants might have. This includes, but is not limited to, any facts that, should they come to light at a future date, may embarrass either the programme or the individual who withheld the fact (e.g. if a member of the team holds a patent or has a financial interest within the research area).

Section J: Declarations & Signatures

You are required to obtain all the necessary signatures. One copy of your application form must contain all original signatures and be submitted along with the electronic version by the deadline for applications. Please note you will only be able to see the signature section on the printed or PDF version of the form.

J5 Will facilities or staff from partner organisations be involved in the project?

Partner would not normally be another academic institution but might be a charity or local authority involved in delivering the intervention. A signature is required where another organisation is providing resources, including financial or data or premises which support the research but which would not have been required just to deliver the intervention.

Section K: Details of Support Requested

The cost details required in this section are those that relate strictly to the R&D costs you wish the PHR programme to support. These are all the research costs which your institution or organisation will incur solely through undertaking this piece of research.

K1: Details of posts and salaries

Please list all members of staff working on the project. Those named as principal and co-applicants earlier in the application form will automatically be inserted under 'Principal and Co-applicants'. Other staff will need to be listed in the appropriate section.

You should state the full time annual costs of members of staff at the start of the project. Full staff costs should be included and should not be reduced to take into account the percentage of time or the duration of time which the person will spend on the project – this operation will be done in K2.

For members of staff which your institution chooses to cost on the basis of average bands rather than actual salary, please state which band you are using and what the full annual cost is.

K2: Annual costs of posts

Those named as principal and co-applicants earlier in the application form (section G) will automatically be inserted under 'Principal and Co-applicants'. Other staff should be listed, as in K1.

You should allocate the individual staff member costs to each year of the project, allowing for increments and inflation. Please note the '% full time on project column' and the years 1-5 cost columns are independent and the % figure is not used to **automatically** calculate the staff costs. You should allow for inflation at your institution's usual rate when calculating salary costs. Use current rates of pay, and build in any known annual increments (again at current rates). If your project is subsequently selected for funding then, once it is underway, you will NOT be able to claim for pay awards retrospectively.

For the years 1-5 columns, the amount you enter should be the cost of the individual to the project, taking into account that the person may not be full time. For example, if the person costs £20,000 and is expected to work 50% of the time on the project, in the percentage column put 50, then £10,000 in year 1, £10,000 plus inflation and any increment in year 2, £10,000 plus inflation and any increments in year 3, etc. Alternatively, if someone is going to work full-time on the project, but only for the last 6 months, you would enter 100 in the % column and 6 in number of months then the cost of their work in the year which is the last one of the project. If the project lasts for several months and someone's involvement

varies over the course of the project, it may be easier to make a separate line entry each time it changes.

It is important to double check that the %, total months and yearly costs information are consistent with the 'Current Annual costs' information in K1 (K1 should show the full current staff costs independent of % etc, whereas the yearly costs in K2 depend on % etc).

Please take care to check whether staff are employed by a Higher Education Institution (HEI) or non-HEI organisation (as this will have an effect on the funding provided – HEI funding is provided at 80% of costs, and non-HEI funding is provided at 100%). All Non HEI staff should be marked by clicking the Non HEI cost circle in the far right column, against the relevant row.

If there are more than 24 co-applicants you will have created an additional electronic application form. You need to enter the salary costs of the additional co-applicants (Sections K1.1 and K2.1) in this form. Once the staff costs in K2.1 have been fully defined, copy the figures in the rows labelled the "Applicant - HEI costs" and "Applicant - non-HEI Costs" to the relevant rows of table K2.1 in the main form. This ensures the costs of all co-applicants involved in the project are included in the total cost of the project calculated by the main form.

K3: Travel and Subsistence

If conferences or international travel are included, a statement naming the conference or purpose of travel and demonstrating the benefit to the project must also be included. Applicants are encouraged to promote and present their findings and travel and subsistence costs relating to this should be included here. Please note that the PHR programme will fund a maximum of two people to attend one international conference, or one person to attend two international conferences. You will need to include the travel and subsistence costs of your Study Steering Committee and Data Monitoring & Ethics Committee if applicable, as well as the cost of attending the PHR welcome meeting (primary research only).

Journeys cost: Enter the total cost of transport for all journeys for destination/purpose. If travel is by car transport, apply your institution's mileage rates (however this should not exceed the DH maximum rate, currently 30p per mile).

Subsistence: Subsistence covers accommodation (if necessary) and meals associated with the travel.

Most Primary Research projects will be invited to attend a welcome meeting. Costs of travel to any welcome meetings at NETSCC should also be included. Welcome meetings will usually be held in Southampton, and up to three members of the team will be invited to attend.

K4: Equipment

Costs of computers are normally restricted to a maximum of £750 each, so a statement of justification must be included for any purchase above this limit.

Equipment costs over £50,000 will normally be funded at 100%. If you are an HEI then please contact us if your equipment exceeds £50,000, as the form will automatically reduce it to 80% and a manual adjustment will therefore need to be made.

If your organisation is an 'eligible body' under HM Customs & Excise Notice 701/30 (VAT: Education and Vocational Training), e.g. you are a university, the cost of any equipment

should include any VAT you have to pay on purchase. If your organisation is not an 'eligible body' you should exclude VAT from your costings.

K5: Consumables

Please itemise and describe the requirements fully (e.g. postage, stationery, photocopying).

K6: Other Direct Costs

Itemise and describe fully anything which does not fit into the previous categories. Please note that in HEIs, recruitment of staff, and general training (e.g. in common IT packages) are costs which should be covered by the indirect costs element of the grant being sought. Training specific to this trial, e.g. in how to deliver a specific intervention, should be itemised and fully described here. External consultancy costs, including service user involvement, can also be claimed here (specifying the hourly rate and total number of hours). Please note that consultants must not be employed by the applicant's institution. Costs for consultants employed by the applicant's institution should be entered in sections K1 and K2.

Additional costs, for example those associated with obtaining any necessary authorisations, should be included here. For randomised controlled trials the cost of obtaining the ISRCTN should also be included. The PHR programme is committed to supporting costs that occur as a result of adhering to regulations and will honour costs as and when they occur but will not support costs that may not happen. If you are unsure as to whether your trial is covered by the Medicines and Healthcare products Agency (MHRA) regulations, you should visit the MHRA website (<http://mhra.gov.uk>) which contains the latest information and a helpful FAQ page.

Any costs associated with publication or presentation of findings (other than those related to travel and subsistence or consumables) should be included.

Any large costs (i.e. greater than £25k) should be further detailed with a breakdown of constituent parts or a timescale profile of the costs.

Section L: Indirect Costs

These costs are calculated on the basis of TRAC (Transparent Approach to Costing) methodology and only apply to Higher Education Institutions. Applicants from other types of institutions should leave this section blank.

L1: Estates Charges

This number is based on the number of full-time equivalent research staff working on the project, using the estates charges set by your institution. The PHR programme reserves the right to examine the full breakdown of the calculation of your institution's estates charges. Where staff from more than one university are working on the project there may be different estates charges for each one. Please list each of these on separate lines.

L2: Indirect Costs Charges

This number is based on the number of full-time equivalent research staff working on the project, using the indirect costs charges set by your institution. The PHR programme reserves the right to examine the full breakdown of the calculation of your institution's indirect costs charges. Where staff from more than one university is working on the project there may be different indirect costs charges for each one. Please list each of these on separate lines.

Section M: Summary of Cost of Project

The figures in this section are completed automatically. NIHR programmes currently fund HEIs at a maximum of 80% of full economic cost (except for equipment over £50,000: 100%). There are no estates charges or indirect costs for non-HEI institutions, therefore the PHR programme will fund a maximum of 100% of directly incurred and directly allocated (non-estates) costs. **Please note that whilst these percentages will be used to calculate the maximum grant applied for, the PHR programme reserves the right to award a grant for less than this where appropriate.**

Section N: Monitoring Information

If you are using a Clinical Trials Unit (CTU) we need the requested information, If not please leave this section blank. The CTU will be aware of this requirement and is able to supply information for your use.

APPENDIX A: Department of Health Monitoring Information

This information is required for monitoring purposes by the DH. The majority of the boxes offer a choice from a drop down menu or simply require applicants to tick boxes relevant to them. However, please note that this section must be completed.

PART 3 – Detailed Project Description

Applicants submitting a Full Proposal must include a Detailed Project Description.

This should be a maximum of 16 pages, using a font size no smaller than 11 point (Arial) and supplied in .PDF format.

Appendices may contain diagrams and charts, but not continuation of text. Applicants should note that any extra pages will be removed upon receipt and therefore not assessed.

Please note some of the information requested in the detailed project description is also included in your application form. Applicants should take care to ensure details provided in both are essentially the same. The detailed project description provides applicants more space to expand on the information provided in the application form.

Please note that these section headings are suggestions only and that they can be amended as appropriate to the particular study

Suggested headings and information to include:

- 1. Project title:** This should be the same as that given in your application form (Section B: Project Details).
- 2. Background:**
 - 2.1. Existing research** - summarise existing research on this topic area, including relevant systematic reviews and other studies, and set out the implications of this for the proposed project.
 - 2.2. Risks and benefits** – summarise the known and potential risks and benefits for study participants and society, including how benefits justify risks

2.3. Rationale for current study: Please note that if the proposed research is to be part of a wider study, the following additional information is required; proof of scientific rigour for the whole study (including study protocols), governance arrangements and assurance regarding data access and permission to include **all** study data in the final report submitted to the PHR programme.

3. Research objectives: Please provide a detailed description of the objectives and purpose of the research. Objectives need to be measurable and time-bound for project monitoring purposes.

4. Research design:

- reference should be made to established research techniques and any adaptations of these for the purposes of the research proposed should be fully explained and justified
- if proposing a randomised trial, describe explicitly how participants will be allocated to trial groups, and describe methods to protect against other sources of bias
- give details of any pilot study that has been carried out using this design including findings and any resulting implications for the proposed research
- describe any "stopping rules" or "discontinuation criteria" for individual subjects, parts of study and the entire study

5. Study population: Please provide a full and detailed list of the planned inclusion/exclusion criteria

6. Socioeconomic position and inequalities: A brief summary of how your proposal will take into account the socioeconomic position of the research participants and potential participants should be included, as well as a description of how the research will attempt to address inequalities.

7. Planned interventions: include both experimental and comparator interventions as appropriate. Are there likely to be any problems with compliance and if so, please provide an estimation of the likely-loss-to-follow-up?

8. Proposed outcome measures: detail both the primary and secondary outcomes. Validated surrogate markers are acceptable where appropriate.

9. Assessment and follow up: please provide details of how / when outcomes will be assessed including:

9.1. Assessment of efficacy/effectiveness: Please describe the methods and timing for assessing, recording, and analysing of efficacy/effectiveness parameters.

9.2. Assessment of harms: Please describe the

- Methods and timing for assessing, recording, and analyzing parameters of harm.
- Procedures for eliciting reports of and for recording and reporting adverse events and other harms.

- The type and duration of the follow-up of subjects after adverse events.

10. Proposed sample size: specify the number of participants and centres (including both control and intervention groups), and recruitment rates. A justification for the assumptions underlying the sample size calculations must be provided.

11. Statistical analysis: clearly state the purpose of any statistical analysis, and do not simply name a statistical test or software package. The proposed type and frequency of analyses must be stated including the selection of participants to be included in the analyses. Describe any planned interim and sub-group analyses.

12. Ethical arrangements: Outline the ethical issues, and arrangements for handling them. How will you inform potential study participants of possible benefits and known risks? How will informed consent be obtained from participants or proposed action where fully informed consent is not possible? Are you using participant information from an existing database? If so, have the participants given their consent for their data to be included in that database for research purposes? If not, is the database exempt under s60 of the Health and Social Care Act 2001?

The PHR programme expects applicants to follow ethical guidelines appropriate to the study and setting proposed. We will scrutinise ethics arrangements as part of the assessment of applications. Applicants must either comply with the Economic and Social Research Council's (ESRC) research ethics framework (<http://www.esrc.ac.uk/ESRCInfoCentre/opportunities/research%5Fethics%5Fframework/>) or obtain approval via the National Research Ethics Service (<http://www.nres.npsa.nhs.uk>).

13. Research Governance: All PHR research must have a nominated sponsor. The Department of Health (DH) expects the employing institution of the lead applicant to undertake this role. Other institutions may wish to take on this responsibility or agree co-sponsorship with the employing institution. The DH is prepared to accept the nomination of multiple sponsors. The DH reserve the right to withdraw from funding the project if they are not satisfied with the arrangements put in place. The application form includes a section where the lead applicant's employer needs to confirm they are prepared to take on sponsorship of this study.

Although primarily designed for trials in a clinical setting, the following website may be a useful resource for evaluation of public health interventions: The Clinical Trials Toolkit website (<http://www.ct-toolkit.ac.uk>) contains information about trial regulation and governance requirements. The Research Governance Framework for Health and Social Care and The Medicines for Human Use (Clinical Trials) Regulations 2004 both require that arrangements for the management of trials involve an element of expert advice that is entirely independent from the lead investigator and their host institution(s).

The PHR programme expects that all primary studies have a study steering committee (SSC), when that is appropriate. Please state in this section if you are going to have an SSC or, if not, you must explain your reasons for not doing so. Please note that if an SSC is not proposed, that decision will be reviewed by referees and the Research Funding Board and it is possible the programme may require that an SSC is established.

Depending on the study design and questions being asked a separate DMEC may be required. Applicants should say if they propose to have a DMEC or that such a committee is not required. Where a DMEC is established it should be independent of the applicants and of the Study Steering Committee (SSC), while reporting to the SSC and (via the SSC) to the PHR programme. Detailed arrangements may need to vary according to the nature of the study and the host institution(s) involved. The PHR programme is keen that the arrangements for each proposed study are proportionate to the type, size and duration of the study involved. We do not require proposed SSC/DMEC membership lists at this stage, but an indication of members who are likely to be proposed (including overseas members) should be included.

If a study needs to comply with these regulations, you must also explain the proposed time period for retention of relevant study documentation and proposed action to comply with 'The Medicines for Human Use (Clinical Trials) Regulations 2004'.

Please note that if your project requires NRES ethics approval, funding will not be released until all required approval documents have been submitted to the PHR programme.

14. Project timetable and milestones: Provide a detailed project timetable including milestones to represent specific steps towards achieving the stated research objectives. Milestones should include a defined start and end date, be measurable, concise and realistic as they will be used for project monitoring purposes. The precise type and number of milestones will depend on the size and nature of the project, although it is expected that between 3 and 10 milestones should be set for each project year. If your project requires ethics approval, you should allow time for obtaining these approvals and submitting appropriate documents to the PHR programme. Time for production of the draft report and draft papers suitable for publication in a peer-reviewed journal should also be included. Other possible milestones could be: participant recruitment and expected recruitment rates; follow-up; closing the database and analysis of the data; staff recruitment, establishing premises and equipment purchase, protocol publication, literature searches, pilot work, interviews, data capture and data cleaning,

If your application is successful, you will be required to submit progress reports against which relevant milestones will be checked. These progress reports will be based on the project timetable and milestones, and will occur at approximately six month intervals. If you are late producing progress reports and a draft final report of the expected standard for the PHR programme, we reserve the right to withhold payments as per the contract.

15. Expertise: Outline the particular contribution each member of the team will make towards the project and the particular contribution that collaborators are intending to make. In addition, give details of supervision arrangements for junior staff involved. The PHR programme suggests teams proposing randomised controlled trials to include input from an experienced trials unit.

16. Members of the Public: The PHR programme recognises the increasing active involvement of members of the public in research and would like to support research projects appropriately. Applicants are encouraged to consider whether the scientific quality, feasibility or practicality of a proposal could be improved with involvement.

Research teams wishing to involve members of the public should outline their plans here stating: the aims of active involvement in this project; a description of the members of the public to be involved; a description of the methods of involvement. Applications that involve members of the public will not be favoured over proposals that do not, but it is hoped that the involvement will improve the quality of the application. INVOLVE has issued guidance for researchers on public involvement in research and the paying of members of the public actively involved in research. These are available via <http://www.phr.nihr.ac.uk> or www.invo.org.uk

17. Justification of support required: Outline staff numbers and grades, timescales, equipment purchases etc that you are requesting the PHR programme to fund. If you propose to purchase expensive equipment, justify fully why you are not proposing to lease it, since this is the DH preferred option.

If the PHR programme is being requested to fund part of a wider study, applicants must provide a clear detailed account of the allocations overall and a full justification. High quality research is essential to improving health. However, the conduct of such work involves activities that entail the burning of fossil fuels thereby releasing carbon dioxide and other greenhouse gases (GHG) into the atmosphere. These gases are changing the global climate with serious implications for human health and for ecosystems. For this reason, it is essential that all sectors of the economy, including the health research sector, take action to reduce their GHG emissions. The PHR programme is committed to reducing the GHG associated with its activities and urges applicants to consider carefully this important consideration when undertaking PHR funded research. Further information about how to reduce GHG emissions is available from: www.carbontrust.co.uk

18. References: Use the Vancouver format (*Author(s). Title. Journal. Year; Volume: Start page - End page*).

FLOW DIAGRAM

As part of your submission, if appropriate to your study, we recommend you provide a flow diagram as this will help the programme understand the design of your study. (This should be a single side of A4 as a .pdf file, please include the project title as a heading for the flow diagram) This should illustrate the study design and the flow of participants. Applicants should also describe complex interventions and controls as accurately and fully as possible within their diagram. If proposing a RCT, we advise you refer to the CONSORT statement and website for guidance (www.consort-statement.org). The .pdf file should be submitted along with your application form (details are provided below in Part 3 of this document).

Finally, when you have completed your Detailed Project Description:

- Create a header containing your project title
- Create a footer showing page numbers.
- Create a .pdf version of your document

PART 4 – Submitting Your Full Proposal Application

The PHR programme requires you to submit your application form, including the signed copy, detailed project description .pdf and, where appropriate, flow diagram .pdf to reach our offices before the stated deadline to process your application. Please ensure that the paper copy contains all the appropriate original signatures. Please remember to print any extra pages (for additional joint applicants) and insert them.

Please note that we cannot grant any time extensions beyond this deadline and that any additional documents enclosed will not be considered by the Board.

Applicants should send the paper copy of their application to:

**Public Health Research Programme
NETSCC
Alpha House
University of Southampton Science Park
Southampton, SO16 7NS.**

Confirmation of receipt: When you submit your application an automatic message will appear on screen confirming successful submission. If for any reason you are concerned that your submission has not reached NCCPHR, please contact a member of the team at info@phr.ac.uk or on 023 8059 9697 (24 hour answer phone).

If you need help

You can contact the team at the PHR programme using the telephone numbers provided on the application form and giving the identification number of the form (click on the telephone icon in the top right-hand corner of the screen). This will enable the team to see your form while they are speaking to you, but not to make changes.

If, after carefully reading all the instructions, you still have difficulties completing your application, please visit the PHR programme website (www.phr.nihr.ac.uk.) which contains a list of Frequently Asked Questions and Answers. If your particular query or problem is not addressed, please telephone 023 8059 9697 and leave a message or contact info@phr.ac.uk A member of the team will call you back as soon as they are able. Please be aware that while every effort is made to answer queries, if the query is made very near the closing date, the PHR programme may not be able to provide a considered response.

**Public Health Research Programme
February 2010**