PUBLIC HEALTH INTERVENTIONS RESPONSIVE STUDIES TEAM PROTOCOL – Nottingham, Loughborough and Lincoln universities

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Short title:	Public Health Interventions Responsive Studies Team
Acronym:	PHIRST
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STUDY PERSONNEL AND CONTACT DETAILS

Sponsor: Contact name	University of Nottingham Ms Angela Shone Research and Innovation University of Nottingham East Atrium Jubilee Conference Centre Triumph Road Nottingham NG8 1DH
Chief investigator:	Elizabeth Orton, Deputy Director of Lifespan and Population Health. Associate Professor and Consultant in Public Health. School of Medicine. Applied Health Research Building, University Park, University of Nottingham, NG7 2RD University of Nottingham elizabeth.orton@nottingham.ac.uk +44 (0) 115 84 66930
Co-investigators:	Professor Lauren Sherar (l.b.sherar@lboro.ac.uk), Loughborough University, UK Professor Mark Gussy, mgussy@lincoln.ac.uk, University of Lincoln Professor Denise Kendrick, denise.kendrick@nottingham.ac.uk, University of Nottingham Professor Pip Logan, pip.logan@nottingham.ac.uk, University of Nottingham Professor Jo Leonardi-Bee, jo.leonardi-bee@nottingham.ac.uk, University of Nottingham Dr Joanne Morling, joanne.morling@nottingham.ac.uk, University of Nottingham Professor Adam Gordon, adam.gordon@nottingham.ac.uk, University of Nottingham Dr Jo Barnes, j.barnes@lboro.ac.uk, Loughborough University Dr Julie Bayley, jbayley@lincoln.ac.uk, University of Lincoln Mrs Pamela Rees, pamela_rees@hotmail.co.uk, PPI

Study Coordinating Centre: Unit of Lifespan and Population Health, School of Medicine, University of Nottingham, University Park, Nottingham, NG7 2RD

SYNOPSIS

Title	Public Health Interventions Responsive Studies Team – Overarching Protocol
Acronym	PHIRST
Short title	Public Health Interventions Responsive Studies Team
Chief Investigator	Dr Elizabeth Orton
Objectives	The overall objective of the PHIRST is to provide timely evaluations of public health interventions. Individual objectives will be set for each project allocated.
Study Configuration	Each evaluation will be configured as appropriate but will be led by one of the three partners: University of Nottingham, Loughborough University or the University of Lincoln.
Setting	The setting will be evaluation-specific, but most are likely to be set in the community.
Duration of study	The overall PHIRST programme is five years from 1 March 2022. Each individual evaluation will have its own duration.
Methods of analysis	Studies will be non-interventional, using the most appropriate observational methodology for that evaluation question.

ABBREVIATIONS

CI	Chief Investigator overall
CRF	Case Report Form
EA	Evaluability Assessment
GCP	Good Clinical Practice
KM	Knowledge Mobilisation
LA	Local Authority
LG	Local Government
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PHIRST	Public Health Intervention Responsive Studies Team
PI	Principal Investigator at a local centre
POG	Project Oversight Group
PPI	Patient Public Involvement
OHID	Office for Health Improvement and Disparities
REC	Research Ethics Committee
R&D	Research and Development department
SMG	Senior Management Group

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STUDY BACKGROUND INFORMATION AND RATIONALE

The NIHR Public Health Intervention Responsive Studies Team (PHIRST) scheme links up academic teams with local authorities to evaluate work that is already happening in local government across the UK. These teams work with Local Authorities to evaluate a range of public health projects, sharing findings to help public health providers best support their communities. The Nottingham-Loughborough-Lincoln team will lead multiple evaluations across a five-year programme.

Patient and public involvement (PPI) is at the heart of our approach, and we will ensure the public and communities are meaningfully involved in all aspects of our work. Not only will they be included in the evaluations, but patients are a core part of both our Oversight Group and central PPI Advisory Group (overseeing the full 5-year programme), with additional PPI Advisory Groups established for each project. Not only will this improve the quality of our research, but it will also ensure our work will benefit patients, carers, the public and their communities.

Each year the PHIRST will be allocated evaluations to undertake and each evaluation will have its own protocol, budget and governance. Results of the evaluations will be made publicly available with an ambition to spread practice and improve the Public Health evidence base.

STUDY OBJECTIVES AND PURPOSE

Along with a non-academic patient and public involvement (PPI) co-applicant and PPI Advisory Group, we will work as a PHIRST team across the UK, with local authorities, communities and the public to evaluate Local Authority projects and share knowledge.

Our aim is to improve the public's health and the opportunity for all to live as healthily as possible (irrespective of where they live, their background or situation), with equity, diversity and inclusion being central to our approach. Achieving this will require innovative practices, building networks and partnerships across a wide geographical area with diverse populations and communities.

PRIMARY and SECONDARY OBJECTIVES

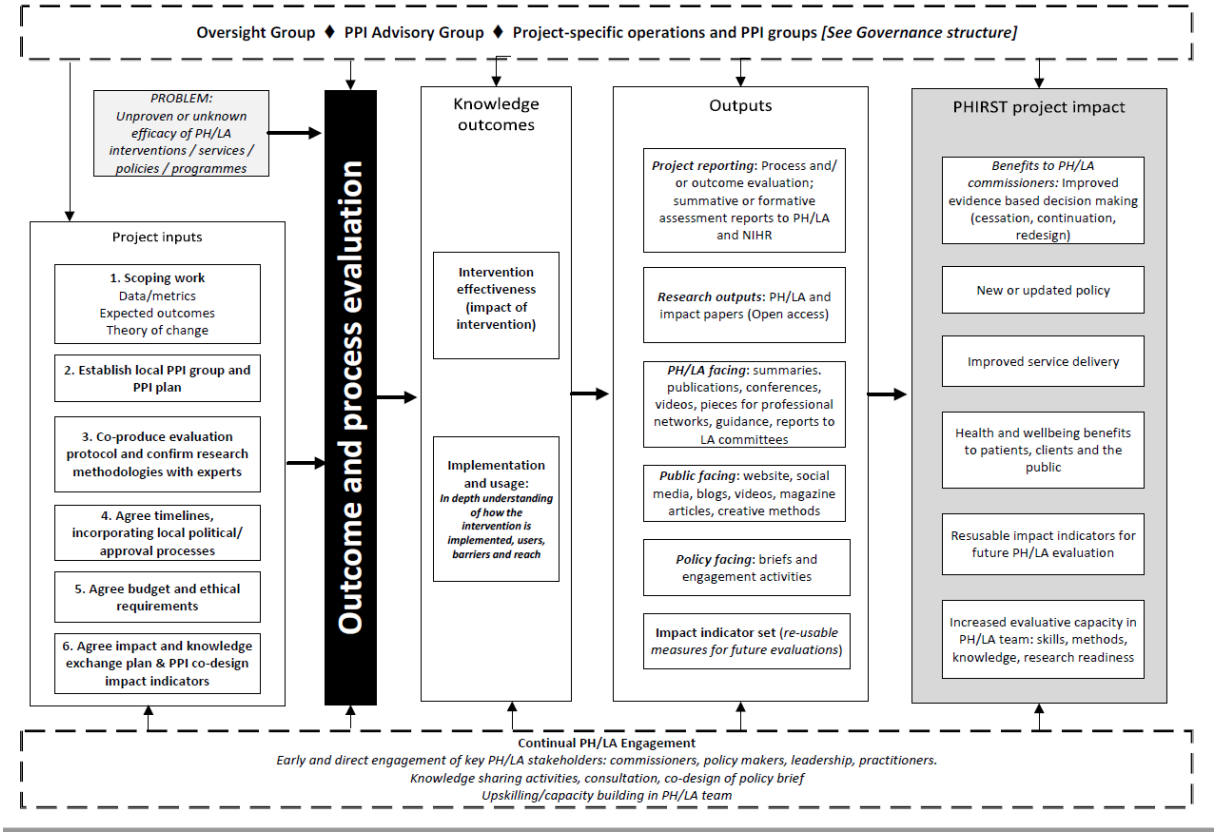
The overall objective of the PHIRST is to provide timely evaluations of public health interventions. Individual objectives will be set for each project allocated.

STUDY DESIGN

STUDY CONFIGURATION

Each evaluation will be configured as appropriate but will be led by one of the three partners: University of Nottingham, Loughborough University or the University of Lincoln. Studies will be non-interventional, using the most appropriate observational methodology for that evaluation question.

Our overarching evaluation approach is depicted in the logic model below.



STUDY MANAGEMENT

The University of Nottingham will be the main contracting organisation with the NIHR and each institution working together to complete the contracting phase. A Research Operations Officer, appointed at the University of Nottingham, will be the responsible liaison for contract management and financial reporting, correspondence with the designated NIHR Programme Manager at NETSCC, assistance with project research staff recruitment, co-ordination and administration of meetings. The three university leads (Orton, Sherar and Gussy) will in turn attend quarterly Leads meetings held by the NIHR.

A **Project Oversight Group** will be independently chaired and have representation from Local Government, the universities, the PPI and scientific experts. Each project will have its own scientific support from the network. We will employ Research Fellows (RF), mentored by Orton/Sherar/Gussy who will lead on the development of the evaluation plan, ethical approvals and data sharing agreements as required, plan the dissemination and knowledge transfer activity and be integral to the evaluation delivery. They will also support PPI members, supported by Rees the PPI lead and Morling the academic PPI lead.

For each evaluation, we will establish a **project-specific Operational Group** (POG) of assigned academic lead (chair), research fellow(s), other co-opted expert members (topic and methodological experts), PPI rep(s). It will oversee the operational day to day management of the evaluation delivery; finances (including reports for oversight group); ethics applications and amendment management (including reports for oversight group); data governance and management; project risks and issues management (including reports for oversight group) and will meet regularly (as and when needed depending on evaluation complexity) during the evaluation.

The **Senior Management Group** (SMG) of Chief Investigator (CI) (EO) and other Co-Investigators will meet bimonthly to provide steer to the operational delivery of the PHIRST. Representatives from the SMG will also meet with the other PHIRSTs as necessary to ensure collaborative working and to learn from each other.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

The overall PHIRST programme is five years from 1 March 2022. Each individual evaluation will have its own duration.

STUDY REGIMEN

SCOPING AND EVALUABILITY ASSESSMENT

Proposals from Local Government (LG), selected by the NIHR PHR programme for evaluation will be acknowledged immediately by our PHIRST Research Operations Officer, who in turn will contact the Local Authority (LA) involved to organise a programme of discussions/workshops with the POG. The workshops will scope the public health problem, refine the evaluation questions, deliverables, timescale and evidence required. If needed, additional meetings will be organised, either by tele/videoconference or in person, with relevant stakeholders in other departments and external partnerships (e.g., voluntary and community organisations, housing organisations, commercial partners) to clarify the scope of the work. Initial details from the LA will guide these conversations, taking into consideration their key dates for delivery to ensure timely and relevant evidence for local decision making.

Based on these conversations, the research fellow(s) in collaboration with the team lead will produce a short evaluability assessment, based on that developed by existing PHIRSTs. This assessment will summarise the context (background to questions, existing data, knowledge and expertise within the council, preferred methodology and desired outputs and dissemination activities) and feasibility of the evaluation. The short evaluability assessment will be shared with the SMG and then discussed with the NIHR PHR programme team.

PROTOCOL DEVELOPMENT

Once continuation on the project is agreed, The SMG will agree a POG with relevant expertise, including contacts across the team's networks where relevant experience or expertise does not lie within the team. A project-specific PPI group will be established that is relevant to the evaluation.

The POG will co-produce a protocol with the LA and PPI members, incorporating the scope, research questions, methods, timescales, budget and deliverables from the evaluability assessment, with input from public or community members as detailed elsewhere. Wherever feasible the team will include at least one practitioner from the LA as part of capacity building and upskilling locally.

The overall work proposal will be shared with the LA partner for feedback and written agreement.

EVALUATION

Based on the LA partner feedback, the research protocol will be finalised and put into action. Work will be conducted with the assistance and quality assurance of the relevant project oversight group. The project will receive leadership sign off and will ensure representation from the public or community at the heart of the research. Wherever feasible practitioner/s from LA will be funded and seconded to work as part of the research team. A flexible approach with each LA will make this possible. Ethics committee approval will be secured through the relevant university committee. Oversight will be provided by the SMG in regular bi-monthly meetings, with advice sought from the POG throughout the project.

Project outputs will be disseminated as described below.

CONTINUOUS IMPROVEMENT AND IMPACT ASSESSMENT

After each evaluation the partners will provide feedback on learning, reflecting what worked well and what could be improved in the next evaluation. We will use this feedback to refine and improve the processes and to share learning across the PHIRSTs.

Following completion of the evaluation we will follow up with each local authority to see how the evaluation recommendations developed in projects are being taken forward and how local infrastructure (e.g., NIHR Applied Research Collaborations, NIHR Clinical Research Networks) and the team can further support the implementation of these findings by making expertise and research capacity available, and by co-developing future funding applications.

COMPLIANCE

The general principles are set out below. However, adjustments may be required for each project as and when details of each are known.

Unintended protocol deviations will be documented and reported to the CI and Sponsor. Protocol non-compliance will be reported without delay by research staff to the CI, who will inform the Sponsor. The CI will ensure that the issue is investigated, and appropriate actions taken. The REC will be notified of any serious breach of its approval conditions, security, confidentiality, or any other incident that could undermine public confidence in the research.

ETHICAL AND REGULATORY ASPECTS

We will use the lead University research ethics committee (or NHS REC if needed) for each application as appropriate and have support from the University of Nottingham Sponsor overall. Compliance and amendments will be managed through the project-specific operational groups and scrutinised by the Project Oversight Group along with data management and research integrity.

ETHICS COMMITTEE AND REGULATORY APPROVALS

Each evaluation will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health

Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible, and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The studies will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A CRF may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators

and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method).

Information about participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be stored on cloud drives with password protected access.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

STUDY CONDUCT

Each study's conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures; back-up and disaster recovery of any local databases and validation of data manipulation. The Research Operations Office or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for

verification of all entries made. In addition, the subsequent capture of the data on the study database will be checked. Where corrections are required, these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

We will adopt an impact literacy approach and co-production from the outset. This enables early and ongoing stakeholder engagement, essential for outputs aligned with our audiences' needs. We will support skills development within public health teams, leaving a legacy of increased evaluative capacity.

Our work will result in two primary knowledge outcomes (see Logic Model): (i) intervention effectiveness (or outcome) and (ii) an implementation/engagement profile (or process). These will help identify barriers, challenges and opportunities key to successful service redevelopment, scaling and policy. Modes of dissemination will include public health facing resources (e.g., publications, pieces for professional networks, conference, free-to access online presentations) and communications (e.g., website, social media, magazine articles, blogs). Supporting principles of transparency and reproducibility, we will produce guidance for service re-design/scaled uptake and a reusable impact indicator set.

Project outputs will enter the health/care system, and society, through multiple routes. Broader (societal) content will be driven through standard broadcasting channels, centralising messages on a dedicated website but establishing links with key networks such as patient/public newsletters, internal staff messages and non-academic media.

Health-related materials will enter the system via stakeholders we have engaged with throughout the process, and by using formats for quick circulation, e.g. policy briefs, white papers. Our impact and communication strategy recognises that high quality materials must be complemented by continued and meaningful engagements with key personnel throughout the system.

USER AND PUBLIC INVOLVEMENT

We are committed to PPI at all stages. At a project's inception, we will co-produce a dissemination, impact and knowledge exchange plan with PPI contributors and commissioners to maximise the accessibility and appropriateness of the results and inform future delivery and funding decisions. PPI members will help write public contributor sections of project reports and we will use the GRIPP2 reporting checklists to improve descriptions of PPI in published papers.

We will develop a standardised process to monitor the impact of PPI activities on our research using e.g., the Public Involvement Impact Assessment Framework (PIIAF). This will ensure each PPI group's activities and the outcome (e.g., changes to study documents) are recorded centrally, thus enabling a process of continual improvement on how we support PPI.

The PPI lead is Ms Rees and our academic PPI lead is Dr Morling, both of whom have significant experience in PPI from diverse communities. Both will work to implement the PPI strategy, oversee the recruitment and training of PPI members, act as a point of contact and ensure the Project-Specific PPI groups have access to the resources they need. The Research Operations Officer will undertake planning and organising the logistics (including access and support needs) for all project related meetings. The PPI Advisory group when recruited will ensure that involvement is aligned to UK Standards for Public Involvement and will provide the Oversight Group with feedback on PPI activities and their impact.

We will co-design the PPI approach that is most appropriate for each study with the PPI Advisory Group and then subsequently the Project-Specific PPI group. For

example, if it is an evaluation of a school-based intervention then the Project-Specific PPI might include students, parents and teachers, or indeed a single panel include people from each group.

Our lead PPI member will ensure appropriate training to aid meaningful involvement. We will set out the expectations regarding participation including how PPI members can expect the research team to correspond, manage their information, document their input etc.

Our **strategic objectives** for patient and public involvement, engagement, and participation are to:

- Ensure that we engage a diverse range of sociodemographic groups appropriate (e.g., in locality and protected characteristics) to each project, from inception through to translation into policy and practice. Many health inequalities are directly associated with socioeconomic, ethnic and age inequalities (e.g., non-communicable disease, uptake of health promoting behaviours and health literacy). We have set aside a significant budget to ensure that we are able to reach seldom heard, disenfranchised communities. Rees (PPI Co-app) has substantial experience in working with Black, Asian and minority ethnic populations and in community development work, domestic violence and homelessness.

- Ensure PPI in our research has bidirectional benefit, that is, it will have added social value to the localities we work in, as well as making important contributions to the evaluation work. Participating in a PPI group may for example provide members with transferable skills such as information management, time management, public speaking etc.

- Offer opportunities for training and research participation capacity building to facilitate meaningful involvement and engagement activities. If we use existing PPI groups our ambition is that we will leave those groups in a stronger position to continue afterwards, with members benefiting from our training.

- Monitor and evaluate our involvement, engagement and participation work to strengthen these activities and support their effectiveness and impact. Learning from the ROWTATE case study described in the PPI section, we will listen to our PPI members and be accountable to them for improving our interaction and their quality of participation experience, using for example, a ‘you said, we did’ approach.

STUDY FINANCES

Funding source

This study is funded by NIHR NIHR135190

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)__Dr Elizabeth Orton_____

Signature: _  _____

Date: _05/07/22_____