NIHR Policy Research Programme (NIHR PRP)

Research Specification

Research call on Supplementary Prescribing by Dietitians and Independent Prescribing by Therapeutic Radiographers

Timetable and Budget

- Deadline for stage 1 applications: 10th July 2017
- Notification of outcome of stage 1: August 2017
- Deadline for stage 2 application: 19th September 2017
- Notification of outcome of stage 2: December 2017
- Award of contract: January 2018 (subject to pre-contract negotiations)
- Budget: £420,000
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Introduction

1. The Department of Health invites Expression of Interest proposals (Stage 1 – see Commissioning Process paragraph) for a single research project to evaluate and inform supplementary prescribing by dietitians and independent prescribing by therapeutic radiographers. Funds of up to £420k are available to support this work, which we expect to take between three to four years to complete. The deadline for applications is the 10th July 2017.

2. This is a significant opportunity to inform policy and implementation in an area of continuing importance for patients, to improve care and ensure people have safe access to the medicines they need.

Extending prescribing to Allied Health Professionals

3. The Department of Health (DH) Non-Medical Prescribing Programme was established to extend medicines responsibilities to professions other than doctors and dentists. NHS England is now responsible for leading the Allied Health Professions Medicine Project. This aims to:
   - Improve patient care without compromising patient safety;
   - Make it easier for patients to get the medicines they need;
   - Increase patient choice in accessing medicines;
   - Make better use of the skills of health professionals;
   - Contribute to more flexible team working across the NHS.

4. The scope of independent prescribing by nurses was expanded in 2006, and independent prescribing by pharmacists and optometrists was enabled in 2006 and 2009 respectively. Supplementary prescribing was extended to physiotherapists, podiatrists and radiographers in 2005.

5. A report on Allied Health Professions prescribing was published in 2009 which assessed the evidence base in this area. This report recommended that independent prescribing by physiotherapists and podiatrists should be taken forward, as a high priority. An engagement exercise took place in 2010, with full

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1 Allied Health Professions Medicines Project, NHS England. For details see: [https://www.england.nhs.uk/ourwork/qual-clin-lead/ahp/med-project/](https://www.england.nhs.uk/ourwork/qual-clin-lead/ahp/med-project/)

public consultations in 2011\(^3\). Proposals were subsequently made to the Commission on Human Medicines (CHM) and the Advisory Council on Misuse of Drugs (ACMD).

6. In 2012, Ministers announced amendments to legislation to allow physiotherapists and podiatrists to independently prescribe medicines, mix medicines prior to administration and prescribe from restricted lists of controlled drugs (subject to amendments to Home Office regulations)\(^4\).

7. In 2015, a public consultation proposing a further extension of medicines mechanisms to additional professions was carried out, and legislative changes were made\(^5\), enabling supplementary prescribing by dietitians, and independent prescribing by therapeutic prescribers.

8. The NHS Five Year Forward View (FYFV)\(^6\) called for new models of care to be developed which integrate services around patients, which will include an improvement of patients’ access to medicines by widening the range of health professionals who can supply, prescribe and administer medicines across the full range of health care settings. The expansion of medicines legislation is one of the key means to fundamentally redesign health services to improve the way patients access care and treatment in the NHS. Changes in the way patients access medicines has the potential to provide more seamless pathways of care by reducing the need to refer patients to another professional purely for the provision of medicines.

9. The extension of medicines mechanisms to further professions such as supplementary prescribing by dietitians and independent prescribing by therapeutic radiographers provides enablers for the health and care system to

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\(^3\)http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Consultations/Liveconsultations/DH_129983
\(^4\)http://www.dh.gov.uk/health/2012/07/response-physios/
http://transparency.dh.gov.uk/2012/09/24/ia-1018/
http://transparency.dh.gov.uk/2012/09/24/ia-1019/
\(^5\)https://www.england.nhs.uk/ourwork/qual-clin-lead/ahp/med-project/dietitians/
https://www.england.nhs.uk/ourwork/qual-clin-lead/ahp/med-project/radiographers/
https://www.england.nhs.uk/five-year-forward-view/
support service improvement through workforce transformation and redesign. For example:

- **Dietetic intervention** is seen as fundamental to the effective management of long-term conditions such as diabetes, renal disease, gastrointestinal disorders, cystic fibrosis and cancer. As people live longer with increasingly complex and multiple long-term conditions, supplementary prescriber dietitians in advanced practice roles have the potential to significantly improve the quality of care that patients with nutritional needs receive through timely access to medicines. This could lead to savings by reducing unnecessary GP appointments, telephone calls with doctors, outpatient appointments and hospital appointments.

- Independent prescribing by therapeutic radiographers working in advanced practice roles is pivotal to fulfilling the radiographer-led pathways of care already being undertaken in radiotherapy. This change in practice could improve experience of care and safety by reducing delays in accessing treatment and creating clear lines of responsibility and accountability for prescribing decisions. This has the potential to improve patient health, avoiding re-referral to GP or hospital consultant for a prescription only and health service freed up as a result. In the longer term, it could also enable new ways of working to improve quality of care, delivering safe, effective services focused on improving the patient outcomes and experience.

10. Dietitians can study to become supplementary prescribers at seven universities in the UK: Coventry, London South Bank, Medway, Robert Gordon (Scotland), Chester, Hertfordshire and West of England.

11. Based on the British Dietetic Association (BDA) database, the expert view of dietetic service managers and current Health and Social Care Information Centre (HSCIC) data, it is estimated that 1354 (30% of the dietetic workforce within the NHS) are currently working at an advanced practice level or above. Given the number of specialist tertiary and children’s centres and community services in the NHS, it is anticipated that 620 dietitians (50% of advanced practitioners) will be eligible, and have an identified role to regularly use supplementary prescribing, which is part of the eligibility criteria for training in supplementary prescribing. It is estimated that, approximately 60 dietitians will be trained in year one and the same number for the next 2-10 years, which is 600 advanced practitioners trained over ten years.
12. Therapeutic radiographers can study to become independent and supplementary prescribers at eight universities: Coventry, London South Bank, Medway, Oxford Brookes, Chester, Cumbria, Hertfordshire and West of England.

13. In November/December 2014 HCPC figures showed that there were 29,578 registered radiographers in the UK of which 90% (26,620) work in the NHS. The diagnostic/therapeutic split of registered radiographers is 86%: and 14%. It is assumed that advanced practitioners make up 20% of the diagnostic and 30% of therapeutic radiographers registered with HCPC.

14. Both prescribing courses are part time, usually take five to six months to complete, and consist of 26 days of study and 12 days assessment in practice. Courses are offered as modules at degree or masters’ level (or equivalent), either stand-alone or as a part of a programme of study at that academic level. Courses are offered once or twice during the academic year. The courses are offered to a multidisciplinary audience and the number of participants from these professions varies considerably. Candidates must satisfy a series of entry requirements, including that there is a specified prescribing role agreed with the employer, that the candidate is working at advanced practice level or equivalent, and there is a designated medical practitioner identified to undertake assessment in practice.

Cost-benefit assumptions

15. Full cost and benefit assumptions for this extension to prescribing practice have been published in the relevant policy Impact Assessments and Equality Analyses7. These include, but are not limited to:

Cost Impact

- The monetised cost of the educational programmes preparing physiotherapists and podiatrists to prescribe independently. This includes both the conversion courses required for a move from supplementary prescribing to independent prescribing; and programmes which enable individuals who currently have no prescribing annotation to achieve supplementary or independent prescribing status. Costs will be incurred only by dietitians and therapeutic radiographers who fulfil programmes’ entry requirements, and who wish to undertake these programmes.
- Time commitment from dietitians and therapeutic radiographers to attend education programmes and any back-fill costs.
- Costs arising from additional governance of the professions.

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• Supervision costs of designated medical practitioners (DMPs).

**Benefit Impact**
• Health benefit from timely treatment, reducing risk of acute conditions becoming long-term conditions (LTC).
• Reduction in GP requirement in terms of time required to prescribe medicines.
• Reduced patient’s time away from work to attend GP practice to obtain a prescription.
• Health benefit to patient from reduced prescriptions and improved medicines adherence.
• Improved communication between GPs and Independent prescribers.

**Other benefits include**
• Improved patient care and safety thereby reducing A&E admissions.
• Improved access to healthcare for all, especially in rural settings and for the elderly.
• Overcoming barriers for supplementary prescribers, e.g. clinical management plans in short-term conditions.
• Potential increase in self-referral to dietitians and therapeutic radiographers, reducing patient care pathway further, particularly in specialist services and for patients with any long term condition(s).

The need for further research on the extension of prescribing

16. Research is required which will contribute to the developing evidence base on widening access to mechanisms for prescribing, supply and administration of medicines to improve patient care. This research should provide evidence to:

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8 This includes, for example:

**Policy Research Programme commissioned research:**
• Extended formulary independent nurse prescribing (Southampton University, 2005) [http://eprints.soton.ac.uk/17584/1/Eval._Extended_Form_...Independent_Nurs_Prescribing_June05.pdf](http://eprints.soton.ac.uk/17584/1/Eval._Extended_Form_...Independent_Nurs_Prescribing_June05.pdf)
• Supplementary prescribing by nurses and pharmacy (Sheffield and Nottingham Universities, 2008) [https://www.sheffield.ac.uk/polopoly_fs/1.43225!/file/Supplementary_prescribing.pdf](https://www.sheffield.ac.uk/polopoly_fs/1.43225!/file/Supplementary_prescribing.pdf)
• Physiotherapist and podiatry independent prescribing (University of Surrey, to be completed in 2017)

Health Education England – North West
• inform decisions about the design of roll out and implementation of extensions to prescribing, including professional development and CPD, for further professional groups;
• inform service redesign, where implementing AHP prescribing can make a difference;
• enable organisations to ensure that qualified AHP prescribers use their prescribing powers, by identifying potential barriers to this;
• increase confidence (if borne out by findings) in the efficacy, safety and cost-effectiveness of extended prescribing (which may lead to increased uptake by organisations);
• shape implementation decisions about services where improved provision of medicines is a part of the sustainability and transformation plans across England.

Research Objectives

17. Research is required to identify effective implementation, and effective prescribing practice. The research should describe prescribing activity and trends in this, and identify innovative service models and practice across care settings, and the outcome of these models, in order to identify effective practice. Across a range of service provision, the research should encompass impact on:
• patient safety;
• patient experiences;
• access and choice;
• patient outcomes;
• costs, efficiency and productivity;
• service design, capacity, and pathways of care;
• communication between prescribers and patients’ GPs
• health inequalities and diversity aspects in relation to the above points.

18. The evaluation should assess:
• quality, effectiveness and cost effectiveness of the supplementary and independent prescribing education programmes;
• relevance and appropriateness of prescribing activity;

- NHS North West
• possible unintended consequences.

19. Other areas which could also be included are:
• comparing the extension of the medicines mechanisms to dietitians and therapeutic radiographers with mechanisms for other professions;
• impact on system performance, including waiting times;
• implications for service redesign;
• barriers to effective implementation;
• changing perceptions of scope of professional practice.

20. Some further considerations draw from the experience of research commissioned on physiotherapist and podiatrist independent prescribing (as yet not all findings have been published). These are for further research in this area, and may be beyond the scope of the current commission, but are as follows:
• longitudinal exploration with robust outcome measures;
• research (with patient/carer views) as prescribing becomes more widespread;
• analysis of medicines management with data capture at individual clinician-level,
• economic evaluation to include impact of substitution, taking account of alternative team structures.

Constraints and requirements

21. The scope of this research is England only, although costs and benefits assumptions in the published policy Impact Assessments are UK wide, given the amendments to legislation apply to the UK.

Research design

22. Whilst the evaluation should meet the aims set out above, methodologies are not stipulated. However, the research outputs should enable us to determine whether the policy has been successful, in terms of published the policy Impact Assessments referred to above. Methods are likely to include:
• scoping phase, to include a review of relevant research;
• analysis of relevant data from the NHS and elsewhere including from clinical audit;
• primary data collection from patients and service providers, via interviews and surveys;
• case studies of services;
• case studies of patients at points in the relevant care pathways.
23. It is expected that the research will cover the range of settings in which dietitians and therapeutic radiographers work, including primary, secondary and tertiary care settings. The research should also cover a range of geographical locations in England, e.g. urban, rural, inner city, and include a range of patient demographics (referring to the Equality Act 2010 and the policy Equality Analyses).

24. Applicants will need to demonstrate how they will maximise participants’ (patients and providers) involvement whilst limiting the negative impact of the research requirements in terms of time and resources. Research proposals will need to demonstrate how they will include patients in both the design and execution of the evaluation.

25. In addition, due to the current relatively small numbers of dietitians and therapeutic radiographer prescribers, the Department of Health is particularly interested in the research proposals’ plans for ensuring that participants’ anonymity is preserved, especially when comparisons are being made between supplementary.

Budget and Timetable

26. Applicants are asked to address the timing and nature of deliverables, maximising staff resources and other options for interim reporting in their proposals.

27. A total of £420,000 is available to deliver and complete the research project.

28. At this stage, we would expect commissioned research to take between 36 - 48 months to complete, to address the evidence needs set-out in this specification. We would like the study to commence by February 2018, with an early interim report later in 2018. Applications will be favoured whereby research can commence on, or soon after, issue of a contract.

Governance Issues

29. A research advisory group including representatives of the National Health Service (NHS) England, NHS Improvement and the Department of Health (DH) will provide guidance for the research, meeting regularly over the lifetime of the research. The successful bidders for this research should be prepared to
review research objectives with the advisory group, and to share emerging findings on an ongoing basis. You will be expected to:

- provide regular feedback on progress
- produce timely reports to the advisory group
- produce a final report for sign off

30. Research contractors will be expected to work with nominated officials in DH, NHS England etc. Key documents including, for example, research protocols, research instruments and reports must be provided to DH in draft form allowing sufficient time for review.
Standard Information for Applicants

31. The sections below provide standard information on different aspects of NIHR PRP funding and will contain details relevant to your application.

General Comments about Applications

32. The National Institute for Health Research Policy Research Programme (NIHR PRP) is a national programme of research dedicated to providing an evidence base for policy-making through the Department of Health. It provides information to the Secretary of State for Health and his Ministers directly and through policy directorates in the Department of Health and covers all aspects of the Department’s policy-making activity.

33. Applications will be considered from other UK countries (Scotland, Wales and Northern Ireland) provided they address the priority areas in a way that is relevant to the needs of the Department of Health (England) and meet all other selection criteria.

34. Applicants are encouraged to submit multidisciplinary applications.

35. Applicants should consider the full range of potential audiences and describe how the research findings could be disseminated most effectively to ensure that the lessons from this research impact on policy and practice.

Research Management

36. Day-to-day management of this research will be provided by the principal investigator. They and their employers should ensure that they identify, and are able to discharge effectively, their respective responsibilities under the Department of Health (DH) Research Governance Framework for Health and Social Care (Department of Health, 2005)9, which sets out the broad principles of good research governance.

37. All successful research involving National Health Service (NHS) and social care users, carers, staff, data and/or premises must be approved by the appropriate research ethics committee (REC) or social care research ethics committee (SCREC). For further information on RECs, please visit the Health Research Authority website: http://www.hra.nhs.uk/

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38. The successful research team must adhere to the Data Protection Act (1998) and the Freedom of Information Act (2000). Effective security management, and ensuring personal information and assessment data are kept secure, will be essential. In particular:

- the research team shall, at all times, be responsible for ensuring that data (including data in any electronic format) are stored securely. The research team shall take appropriate measures to ensure the security of such data, and guard against unauthorised access thereto, disclosure thereof, or loss or destruction while in its custody;
- personal data shall not be made available to anyone other than those employed directly on the project by the research team, to the extent that they need access to such information for the performance of their duties. The research team should show that they have experience of and access to appropriate databases and IT support to maintain data security and integrity and that meets regulatory standards.

39. For any research involving clinical trials, the successful team will be expected to be familiar with the Medical Research Council (MRC) Framework for Evaluating Complex Interventions (MRC, 2000)\textsuperscript{10}, and to follow the principles of the MRC Guidelines for Good Clinical Practice in Clinical Trials (MRC, 1998)\textsuperscript{11} in proposing structures for oversight of such trials and comply with the Medicines for Human Use (Clinical Trials) Regulations 2004.

40. The Institution leading the proposal should confirm that it has the capacity and is prepared to take on sponsorship responsibilities for clinical trials undertaken as part of the programme. Where the proposal includes a proposal for multi-site clinical trial activities the research unit should demonstrate that they have the experience of governance and management of clinical trials across multiple clinical trial sites.

**Risk Management**

41. Applicants should submit, as part of their proposal, a summary explaining what they believe will be the key risks to delivering their research, and what contingencies they will put in place to deal with them. Please ensure this is detailed in the Management and Governance section of the online application form.

\textsuperscript{10} Medical Research Council. (2000). A framework for development and evaluation of RCTs for complex interventions to improve health [Online]. [cited 2008 March 26]; Available from URL: \texttt{http://www.mrc.ac.uk/}

42. A risk is defined as any factor which may delay, disrupt or prevent the full achievement of a project objective. All risks should be identified. The summary should include an assessment of each risk, together with a rating of the risks likelihood and its impact on a project objective (using a high, medium or low classification for both). The risk assessment should also identify appropriate actions that would reduce or eliminate each risk, or its impact.

43. Typical areas of risk for an evaluation study might include ethical approval, site variation in data gathering, staffing, resource constraints, technical constraints, data access and quality, timing, management and operational issues; however, please note this is not an exhaustive list.

**Patient and Public Involvement (PPI)**

44. The NIHR Policy Research Programme expects the active involvement of patients and the public (e.g. service users and carers) in the research that it supports, where appropriate. However, the nature and extent of patient and public involvement (PPI) is likely to vary depending on the context of the study. Applicants should describe how the issue of PPI will be addressed throughout the research process. For example, this could include patient and public involvement in refining research questions, designing research instruments, advising on approaches to recruitment, assisting in the collection and analysis of data, participation or chairing advisory and steering groups, and in the dissemination of research findings.

45. Applicants are required to detail what active involvement is planned, how it will benefit the research and the rationale for their approach. PPI needs to be undertaken in a manner that acknowledges that some people may need additional support, or to acquire new knowledge or skills to enable them to become involved effectively (see INVOLVE publications for guides for researchers). Applicants should therefore provide information on arrangements for training and support. In addition, applicants should note that a budget line for the costs of PPI is included in the finance form. Where no PPI is proposed, a rationale for this decision must be given.

46. For further information and guidance about PPI, please visit the INVOLVE website: [http://www.invo.org.uk/](http://www.invo.org.uk/).
Outputs and Reporting Arrangements

47. The research team will be expected to provide regular progress reports over the lifetime of the research and will be provided with a progress report template to complete at regular intervals. In addition to describing progress, these reports will allow researchers to indicate any significant changes to the agreed protocol, as well as setting down milestones for the next reporting period, giving an update on PPI and any publications or other outputs. Information on emergent findings that can feed more immediately into policy development will be encouraged and should be made available as appropriate.

48. A final report on the research, with an accessible executive summary, will be required within one month following completion of the research. The report will be peer reviewed and may be circulated among relevant stakeholders within the Department of Health and its partners. Once the study is completed, a summary of the final report will be placed in the public domain, on the Policy Research Programme Central Commissioning website. This is where the outputs resulting from expenditure of public funds are made available for public scrutiny so it is important that the summary of your final report is easily accessible to the lay reader.

49. Research contractors are obliged to give at least 28 days notice before submission of any publication arising from research funded by the NIHR Policy Research Programme. In this instance, ‘publication’ concerns any presentation, paper, press release, report or other output for public dissemination arising from a research project funded by the NIHR PRP. Research contractors remain under an obligation to provide notice even after the contract has ended. Publication of NIHR PRP-commissioned research is subject to prior consent of the Secretary of State, which will not be withheld unreasonably and cannot be withheld for more than three months from the time the publication is submitted.

Finance

50. The duration of the research and individual projects within the contract will be no longer than is consistent with high quality studies. In assessing proposals, the Department will be seeking value for money as well as scientific excellence and, in particular, the potential for policy impact which is key.

51. Applicants are asked to address the timing and nature of deliverables, maximising staff resources and other options for interim reporting in their proposals.
52. Applicants should always provide an indicative budget for the planned research.

53. Costing can include up to 100% full economic costing (FEC) but should exclude output VAT. Applicants are advised that value for money is one of the key criteria that peer reviewers and commissioning panel members will assess applications against.

54. All applications are expected to start within 2 months of funding being agreed, subject to pre-contract negotiations and specific requirements.

**Dissemination**

55. Applicants should describe how the research findings could be disseminated most effectively, ensuring that results of this research impact on policy and practice in the NHS, DH, and/or in social care.

56. Publication of scientifically robust research results is encouraged. This could include plans to submit papers to peer reviewed journals, national and regional conferences aimed at service providers, professional bodies and professional leaders. It might also include distribution of executive summaries and newsletters. Less traditional dissemination routes are also welcomed for consideration.

**Transparency**

57. In line with the government’s transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: https://www.gov.uk/government/publications/procurement-and-contracting-transparency-requirements-guidance.

58. If you wish to view the standard terms and conditions of the NIHR Policy Research Programme contract, please go to: www.nihr.ac.uk/prp.

**Application Process**

59. To access the research specification and application form, please visit the NIHR Policy Research Programme Central Commissioning Facility (PRP CCF) website at www.nihr.ac.uk/prp
60. The PRP runs an online application process and all applications must be submitted electronically. No applications will be accepted that are submitted by any means other than the online process. **Deadlines for the submission of outline and full research applications occur at 1.00 pm on the day indicated and no applications can be accepted after this deadline.** We strongly recommend that you submit your application on the day before.

61. Once the 1.00 pm deadline passes, the system shuts down automatically and CCF Programme Managers are unable to re-open it. If you are experiencing any technical difficulties submitting your application, please contact the CCF on 0208 843 8027 in good time, before 1.00 pm on a closing date.

62. Applicants are expected, before submitting applications, to have discussed their applications with their own and any other body whose co-operation will be required in conducting the research.

63. In order for your full application to be validated and submitted you are required to gain electronic approval from the relevant authorities before the application deadline. The Declarations page must be approved:

a) by the **Lead Applicant** to confirm that the content of the application is complete and correct.

b) by an **administrative** or **finance officer for the contracting (host) institution** to confirm that the financial details of the application are correct and that the host institution agrees to administer the award if made.

c) by a **Head of Department** or **Senior Manager** to confirm that they have read the application and that, if funded, the work will be accommodated and administered in the named institution and that the applicants may undertake the work.

64. Until this is completed the lead applicant is unable to validate and submit the application.
**Commissioning Process**

65. The standard NIHR PRP commissioning cycle includes the following steps:

66. In the standard 2 Stage Commissioning, **outline applications** or, in case of Expression of Interest (EOI), **short EOI applications** will be short-listed by a Commissioning Panel. Incomplete applications, applications too remote from the issues set out in the research specification, or applications that have clearly inadequate presentation or methods may be rejected at this stage.

67. Applications that are successfully short-listed by the Commissioning Panel will proceed to Stage 2 of the application process and will be invited to submit a Stage 2 full application for consideration.

68. All full applications submitted to NIHR PRP will be peer-reviewed by both stakeholder and independent academic referees. Wherever time permits, applicants will be given one week to respond to the peer reviewers’ comments.

69. Full applications, peer reviewers’ comments and any responses to those comments will then be considered by the Commissioning Panel, which is comprised of independent experts (possibly with observers from other government departments and executive agencies), who will advise the NIHR on which applications are most suited to receive funding. The Panel will be informed by the reviewers’ comments and any responses made to these comments by the researchers. However, it is ultimately the responsibility of the Panel to make any funding recommendations to the Department of Health.

**Selection Criteria**

70. The Commissioning Panel members are directed to consider applications against the criteria stated in this research specification as well as selection criteria detailed below:

- **RELEVANCE** of the proposed research to the research specification
- **QUALITY** of the research design
- **QUALITY** of the work plan and proposed management arrangements
- **STRENGTH** of the research team
- **IMPACT** of the proposed work
- **VALUE** for money (justification of the proposed costs)
- **INVOLVEMENT** of patients and the public

**Contacts**

71. General enquiries regarding the application and commissioning process can be directed to the NIHR PRP Help Desk by telephone at **0208 843 8027** or by email to **prp@nihr.ac.uk**