NHS
National Institute for Health Research

Invention for Innovation (i4i)

Guidance for Applicants

Call 14 Product Development Awards

TABLE OF CONTENTS

1 Introduction

1.1 Purpose

The NIHR Invention for Innovation (i4i) programme is a translational funding scheme which advances healthcare technologies and interventions for increased patient benefit in areas of existing or emerging clinical need. It supports research and development of medical devices, active implantable devices and in vitro diagnostic devices.

There are two funding streams; Product Development Awards (PDA) and Challenge Awards. PDA supports the R&D of medical technologies in any area of existing or emerging clinical need. The Challenge Awards are based on themed calls in areas of existing or emerging healthcare need. The expected output of i4i funding is an advanced or clinically validated prototype medical device, technology or intervention.

The objectives of i4i are to:

- Accelerate the development and uptake of innovative products, technologies and interventions for the benefit of patients in the NHS.
- Support collaborative English-led projects targeting unmet healthcare needs.
- Provide translational funding for projects which have demonstrated ‘proof of principle’ and have a clear pathway towards clinical adoption and commercialisation.
- De-risk projects and make them attractive to follow on funders and investors.

1.2 Essential requirements

- Projects must have already demonstrated ‘proof of principle’. Applicants are expected to have generated experimental data to support the case for further development and illustrate technical feasibility. Early stage research or discovery science is not fundable.
- A minimum of two organisations must be involved from an NHS Trust, NHS service provider, Higher Education Institution (HEI) or Small to Medium Enterprise (SME).
- Lead applicants must be based in England.
- Work packages must not include animal studies. If animal studies are required as part of the project, we expect applicants to seek parallel funding to cover such studies, details of which can be provided in the application form.
- Proposals must set out a commercial strategy that takes into account the regulatory pathway, IP management, commercial barriers, health economics and route to market.
- Proposals must present a plan for adoption of the technology into the NHS and other healthcare systems.

1.3 Eligibility

All proposals must meet the essential requirements of the i4i programme.

Funded activities:

- Research and development of medical devices, active implantable devices and in vitro diagnostic devices as defined by the relevant EU directives, across all areas of existing or emerging healthcare need (for examples see http://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/invention-for-innovation/).
- Product development required to enable a technology for clinical use; work packages may comprise all aspects around manufacturing, intellectual property protection, freedom to operate analysis and market analysis, business case development, etc.
- Research and development of techniques or technologies from a different industry sector, which could have a potential impact if applied in a healthcare setting.
- Feasibility studies if a technology from a sector other than health is being developed
- Studies to provide data relating to safety and effectiveness of a device, including first-in-man and pivotal studies.
- Health economic analyses and clinical utility studies, looking at a device's real-life implementation and use.
- CE marking and other regulatory requirements, including any associated safety trials.
- Activities associated with the adoption of new technology.
- Training associated with the implementation of new technology.

The i4i programme will not fund:

- Minor or incremental changes to technologies or interventions in current clinical use.
- Projects involving small molecule drugs and biologics, including vaccines and gene therapies.
- Projects involving stem cells.
- Projects involving cosmetic products.
- Projects that involve work on animals or animal tissue.
- Early stage or basic research.
- Evaluation or clinical trials of fully developed products or interventions, which have already been adopted within another NHS organisation or have a history of NHS use.
- Studies to improve the understanding of biological processes.
- Studies on the impact of interventions on service delivery and management.
- Products to be used only in hospital information, administration infrastructure and other related software.
- Methodologies clinically assessing or validating an existing or newly developed technique or technology.
- Professional training.
- Development of innovation or knowledge networks and healthcare technology cooperatives which aim to accelerate the development of innovative technology products.

Applicant eligibility

The lead organisation must be based in England and it can be any of the types of eligible organisation listed below. Overseas collaborators are permitted but will not be eligible to receive any funding. Their role must be clearly described in the application.

The following types of organisations are eligible for funding:

- SMEs (including start-up or ‘spin-out’ companies);
- NHS organisations (including NHS Trusts and NHS Foundation Trusts), and equivalent UK authorities;
- Universities, research institutes and not-for-profit organisations.

A collaboration of two or more of the above is eligible. Applications which involve partnerships between a university and its associated NHS Trust are considered an eligible collaboration. If support for a clinical trial is requested, one of the partners must be an NHS organisation or other NHS service provider which has agreed to be the sponsor of the trial.

It is possible that an organisation outside England can request funding as a co-applicant, if an appropriate case is made. We would expect the application to make a strong case that the chosen co-applicant was the organisation best placed to provide input to the planned research.

Specialist services or expertise may be brought into the team through consultancy or sub-contract arrangements, however, appropriate justification must be provided. Sub-contractors may be based outside of England.

The day-to-day running of your project should be handled through a project manager. While it is acceptable for the lead applicant to act as the project manager, for larger consortia in particular we would expect you to employ a dedicated project manager on a part-time basis.

For projects with a strong clinical emphasis it is expected that project teams encompass all relevant expertise required for clinical development and implementation, including clinical trial methodologists, statisticians, nurses, allied health professionals and commissioners.

The involvement of small and medium-sized enterprises (SMEs) and/or early-stage companies in applications is particularly welcome. Large companies may be involved, but are unlikely to be supported with i4i funds.

For all collaborations where a partner is providing in-kind contributions, the exact nature of the commitment of each partner must be clearly detailed.

2 Funding Conditions

2.1 Project duration and amount

Projects are awarded funding for up to 3 years.

There is no upper or lower set limit for the size of these awards, although typically projects range from £300k-1m in value. Applicants should request a budget appropriate for developing their innovative solution to the point at which it is either attractive to follow-on developers/investors or is ready for deployment. All funding requests will be scrutinised to ensure they are eligible within the appropriate guidelines (see FINANCE GUIDELINES).

2.2 Project finances

Stage 1 Application Forms should indicate a reasonably accurate estimate of the total funds required. Short-listed applicants must declare an actual amount and a detailed cost breakdown in their Stage 2 Application Form. It is accepted that this final figure may differ slightly from the initial estimate given at

Stage 1.

3 Application Process

3.1 Registration and creating an application

The i4i programme operates on a two-stage application process.

Applications must be submitted online using the NIHR Central Commissioning Facility's Research Management System (RMS). Applicants and co-applicants need to register their details, including a professional and academic CV.

Lead applicants must provide an ORCID iD in their application. The NIHR is an ORCID member and requires researchers to obtain this persistent digital identifier that distinguishes you from other researchers. Without it, your application will not be validated and you will not be able to submit. If you don't already have one, we recommend that you register for your ORCID iD as soon as possible.

The lead applicant must create the application, but the application can be jointly completed with any co-applicants. Co-applicants can be added to the application at any time and will receive an automatic email by the RMS which will prompt them to accept their inclusion and later to consent to the application being submitted with their participation. All co-applicants must accept their invitation to participate in the application by the submission deadline for the application to be eligible for submission.

3.2 Validating and submitting your application

When the application form is complete it must be validated prior to submission. This will highlight any omissions in the form and allow these omissions to be corrected. After successful validation the lead applicant may submit the application.

Once you have submitted your application, an i4i specific reference number will be generated. The application will be automatically considered for funding once the funding call closes.

3.3 Stage 1 Applications

Refer to the terms and conditions under which the award will be made prior to applying for funding. These terms are set out in the NIHR standard contract and are broadly non-negotiable. The contract will be concluded between the lead organisation and the Department of Health, which will be managed by the NIHR Central Commissioning Facility.

Stage 1 applications should be submitted on the RMS **before 1pm** on the advertised closing date.

3.4 Shortlisting

Assessment of Stage 1 applications is made by an expert Selection Panel which is comprised of academic, clinical and commercial expertise. Applications are scored against the i4i programmes assessment criteria.

Stage 1 applications will be shortlisted and successful applicants will be invited to prepare and submit a Stage 2 application form. Details of the Stage 2 application process will be provided at that time.

3.5 Full applications and interviews

All invited Stage 2 applications are subject to independent peer review. Applicants will see the anonymised peer reviewers' comments and will have the opportunity to respond in writing. The application form, peer reviews, presentation and the applicant's rebuttals are all taken into consideration by the Selection Panel in reaching their funding decision.

Stage 2 applications should be submitted on the RMS **before 1pm** on the advertised closing date.

All Stage 2 applicants must present their project proposal in person to the Selection Panel at a Selection Panel meeting. The interview takes the form of a short presentation followed by a question and answer session.

Applications are treated as confidential and all steps are taken to ensure confidentiality is maintained. In line with Department of Health policy, i4i will publish summary minutes of Selection Panel meetings. Please refer to our Confidentiality Guidance for further details.

3.6 Post award process

Funding offer

Once your application has been recommended for funding, we will provide feedback as agreed with the Selection Panel. Successful applicants are expected to start their project within four months of the funding notification, subject to satisfactory completion of due diligence and a fully signed contract. The Department of Health reserves the right to withdraw the funding offer at any time after six months of the funding notification.

Due diligence

The due diligence process starts after submission of stage 2 applications. Its purpose is to highlight any potential areas of weakness within the project, allowing the Selection Panel to make recommendations how to address these weaknesses and to identify the level of project monitoring that will be required. Projects recommended for funding will have to satisfy all conditions imposed by the Selection Panel and the i4i secretariat before the funding agreement can be put in place.

In addition to any changes to the work plan that may be requested by the Selection Panel, further information may be requested on project finances, project management, intellectual property and commercialisation. Funded applicants may be required to engage with an independent advisor for the revision of the project plan or any other project elements.

Finances

The project finances will be thoroughly scrutinised to ensure that all requested costs meet the NIHR finance guidelines (see **FINANCE GUIDELINES**); any costs that cannot be fully justified may have to be adjusted. The Department of Health reserves the right to negotiate the price it is prepared to pay for the work, based on the cost of the application and its operating constraints.

For collaborative partnerships where a partner is providing in-kind contributions, the exact nature of the commitment of each partner must be clearly detailed. Small and medium-sized enterprises (SMEs) and/or early-stage companies may be required to provide accounts and cash flow forecasts in order to demonstrate their capability to support a project throughout its lifetime.

The financial risk of i4i awards will be managed through a number of project-specific go/no go points or milestones, which could be technical, clinical, regulatory, intellectual property or commercial milestones. These milestones will be linked to funding stage gates as defined in the payment schedule of the contract. If a milestone is not achieved, payment will not be released until appropriate corrective steps have been taken to address any issues.

Contracting

Once due diligence has been completed, the NIHR standard contract will be put in place between the lead organisation and the Department of Health. As part of the contracting process, a reporting and a payment schedule will be negotiated with the lead organisation, based on the proposed deliverables and milestones. The contract will be managed by the NIHR Central Commissioning Facility; all i4i projects will be actively monitored.

4 Assessment Criteria

Stage 1 and stage 2 applications will be assessed against the following criteria:

- Clinical need, health economic case and impact on the NHS and patients
- Level of innovation
- Case for further development based on work to date and evidence from the literature
- Quality of the project plan, including the technological content and risk mitigation strategy
- Strength of the project team and management arrangements
- Intellectual property (IP) and commercialisation strategy
- Value for money
- Patient and public involvement

Clinical need, health economic case and impact on the NHS and patients

The proposed research must be highly relevant to the needs and healthcare priorities of the NHS. A clear case has to be made how the proposed device, technology or therapy might influence clinical practice. The clinical need and advantages over the current gold standard and any constraints in adoption must be clearly articulated. Evidence must be presented that a novel technology, a novel intervention or a novel clinically adopted technology will be the ultimate output of the project, delivering a clear benefit to patients and/or practice within the NHS.

Level of innovation

Applicants must demonstrate how the proposed device, technology or intervention presents a significant level of innovation, providing an advance over currently commercially available products. The application must contain an explanation of how adoption of the technology would change clinical practice and how the project will generate data to drive adoption.

Case for further development based on work to date and evidence from the literature

Applicants will need to provide evidence to support the case for further development. Applicants are encouraged to provide details of key data generated in prior studies and that support the project in the appendix of the application form, and any claims or assertions made about the technology in the Case for Support section, including the plain English summary, must have references provided.

Quality of the project plan, including the technological content and risk mitigation strategy

The proposed project must be focused on a specific clinical application, with the characteristics of the proposed technology or intervention clearly defined. Project aims and objectives must be realistic in terms of time and resources requested. It is vital to add as much detail as possible on research design and methodology. The project plan must adequately address aims and objectives, identify the main technical and regulatory barriers and key risks to successful completion of the project and propose appropriate steps to mitigate these risks. If a favourable ethical opinion is required to carry out the project, evidence for approval must be provided before project start or before start of the respective work package. If ethical approval is only required in later stages of the project, it will be a distinct deliverable of the project and part of a funding stage gate.

A clear set of measurements which define the success of the project must be outlined; the key risks to delivering the research and the contingencies that will be put in place to mitigate them identified. Ideally a risk register should be maintained and updated during the timeline of the research.

All projects must adhere to the research governance framework for health and social care. Projects involving clinical trials should follow the MRC guidelines for good clinical practice in clinical trials. Researchers designing or undertaking clinical trials are also encouraged to consult the Clinical Trials Toolkit. This NIHR resource is an innovative website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although the Clinical Trials Toolkit is primarily aimed at publicly funded Clinical Trials of Investigational Medicinal Products, it will also provide researchers and R&D staff working on trials in other areas with useful information and guidance.

Strength of the project team and management arrangements

Arrangements for managing the project must be adequate and roles of team members must be clearly described. Project teams are expected to have included expertise in all areas relevant to develop the proposed device, technology or intervention towards commercialisation. Any evidence of previous product development should be included. It is possible to request resources for external expertise, e.g. consultants for health economics or regulatory development. Teams are advised to appoint a Project Manager to coordinate and oversee project activities.

Intellectual property (IP) and commercialisation strategy

All background and any potentially arising foreground IP must be described in the application. An initial freedom to operate opinion must be provided, referencing any third parties' rights which may affect the development or commercialisation of your device or technology. A strategy should be put forward as to how third party rights will be managed to allow for further development and commercial exploitation.

IP arrangements between collaboration partners and with consultancies and sub-contractors must be regulated by appropriate agreements. The Lambert Toolkit provides model agreements for collaborations between universities and companies.

Market opportunities, both domestic and global, and the expected impact of the proposed technology or intervention must be described. A strategy for the commercial development of the technology or intervention must be presented. At the end of the project applicants must deliver an exploitation plan, including further IP and commercialisation strategy and potential sources of onward investment.

Value for money

All requested costs must be sufficiently justified and essential for the proposed work; however, it is expected that all applications aim at achieving real clinical impact, so the requested amount should allow for effective development of the device, technology or intervention. Taking into account the expected benefits of the proposed work and the level of funding requested, the proposal must provide value for money. Any funds requested for NHS support and treatment costs must be appropriate and justified.

Patient and public involvement (PPI)

The NIHR expects active involvement of patients and the public in the projects it supports. It is anticipated that most i4i projects will have a significant PPI component, which must be clearly and fully described. Applicants should identify the relevant patient/user group(s) for their application and engage with those groups at an early stage. To make the contents of your application and the implications of your project clear to members of the public, but also commissioning boards and reviewers, a plain English summary is required (see **Plain English summary** for further details). Further guidance and PPI resources can be found under **PATIENT AND PUBLIC INVOLVEMENT**.

5 Post Award Monitoring

5.1 Progress and financial reports

i4i will oversee the management and progress of funded projects based on the deliverables and milestones agreed in the contract. An i4i project manager will be assigned to your project. We will use quarterly progress reports, email communication, phone calls and site visits to evaluate progress and the achievement of deliverables and milestones.

As payments will normally be made quarterly in arrears (at the end of March, June, September and December), you will also be required to provide quarterly expenditure reports and an annual statement of expenditure. Universities and NHS organisations will be paid as agreed in the payment schedule. Commercial organisations are required to issue invoices at the end of each quarter; any deviation from the scheduled payment in the contract must be thoroughly explained. Any funding not spent at the end of each financial year may be recovered by the Department of Health or set off against any future payments. In such situations, a new payment schedule will be issued.

When a scheduled payment is linked to a funding stage gate, the project team must clearly demonstrate that the contractually defined milestone has been achieved before any payment will be released. If a milestone is not achieved, payments may be withheld until the milestone has been achieved or an appropriate contingency plan has been agreed.

5.2 Return on investment

The NIHR funds a wide spectrum of health research and is keen to support the exploitation of products or treatments developed under its funded research to ensure that the benefits are not lost to UK patients and there is a return on its investment. The return on investment will depend on the nature of the funded project and the level of funding provided and will be agreed as part of the NIHR commercialisation agreement. Potential forms of return on investment include:

- Patient benefit, such as reduced morbidity or mortality, and improvements in quality of life
- Cost savings, resulting from innovative practice methods developed within the public health and social care systems funded by the NIHR
- Commercial return in the form of a share of revenues generated through IP licensing or consultancy, taking shares in new businesses created, or seeking product or service discounts, thereby generating cost savings
- Public good, such as a demonstration of the impact of NIHR funding on the health and prosperity of the nation

When a project team wants to make commercial use of any IP generated during an i4i project, whether during the life of the project or at any time after the project has ended and is ready for commercialisation, written consent must be obtained by the Department of Health and an income- or equity-based revenue share will be agreed. We may consider requests for early agreement of commercialisation terms. The terms as set out in the NIHR commercialisation agreement will form the basis for negotiation.

6 Key Dates

The key dates for Call 14 are shown below:

Event	**Date**
Call Launch	26th April 2017, 9am
Stage 1 Deadline	7th June 2017, 1pm
Stage 2 Launch	2nd August 2017, 9am
Stage 2 Deadline	27th September 2017, 1pm
Panel Meetings	28th and 29th November 2017

7 Contact Details and Further Information

We wish to ensure that potential applicants fully understand what is needed in their applications before they submit them. We are happy to discuss the general principles of strong proposals prior to the deadline, although we cannot advise on the specific content of an application.

Enquiries may be made by email to i4i@nihr.ac.uk. Alternatively the i4i Secretariat can be contacted on +44 (0)20 8843 8015

NIHR can offer further support and advice on your application for funding through a number of its organisations, details of which are provided below:

NIHR Diagnostic Evidence Co-operative's (DEC's)

NIHR DEC's provide support and advice on generating information on clinical and cost-effectiveness

of in vitro diagnostics. For more information please visit http://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/infrastructure/diagnostic-evidence-co-operatives.htm

NIHR Health Technology Co-operative's (HTC's)

NIHR Healthcare Technology Co-operatives are centres of expertise that work collaboratively with industry to develop concepts of new medical devices, healthcare technologies and technology-dependent interventions that improve treatment and quality of life for patients. For more information please visit http://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/infrastructure/healthcare-technology-co-operatives.htm

NIHR Research Design Service (RDS)

NIHR funds the Research Design Service (RDS) to provide design and methodological support to health and social care researchers across England to develop grant applications to the NIHR and other national peer-reviewed funding programme. For more information please visit http://www.rds.nihr.ac.uk

Appendix: Application Finances

Required Reading

Prior to completing the finance section of the application it is important applicants have a good understanding of the following:

Attributing costs of health and social care Research and Development (AcoRD) guidance

The AcoRD guidance clarifies the distinction between the three categories of costs associated with non-commercial research studies/programmes:

- Research Costs
- NHS Support Costs
- NHS Treatment Costs

Attributing the costs of health and social care research and development (AcoRD):

NIHR will only fund activities attributed to Research Costs. However, for funding panels to be able to make an overall value for money judgement, we require that both NHS Support Costs and NHS Excess Treatment Costs are outlined in the finance form.

We strongly recommend that applicants familiarise themselves with these definitions, and consult:

AcoRD Annex A: List of common research activities attributed to the Research Costs, NHS Treatment Costs and NHS Support Costs:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/351185/AcoRD_Annex_A_-__List_of_Common_research_Activities_March_2013_for_publication.pdf
AcoRD Annex B: FAQ:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/484554/Annex_B_AcoRD_FAQs__Dec_15.pdf

NHS England Guidance on Excess Treatment Costs

Before applications are submitted to the NIHR, it is our expectation that applicants have already contacted the appropriate NHS commissioner(s), to discuss and secure (in principle) the NHS excess

treatment costs relating to the study.

NHS England has been working in consultation with the Department of Health (DH) and other key stakeholders to develop an NHS England strategic plan on the process and funding of Excess Treatment Costs that delivers DH policy. As a result, NHS England has published new guidance, to help clarify the rules and expectations, which is available on the NHS England website. We strongly recommend that applicants familiarise themselves with this guidance: https://www.england.nhs.uk/ourwork/research/etc/

Clinical Research Network (CRN) Study Support Service

Before applications are submitted to the NIHR, it is our expectation that applicants have already contacted the appropriate NIHR Clinical Network(s), to discuss and secure (in principle) the NHS support costs relating to the study.

The NIHR Clinical Research Network (CRN) supports researchers and the life-sciences industry in developing, setting up and delivering high quality research to time and to target in the NHS in England.

For any study that is eligible for applying for CRN support, whether commercially or non-commercially sponsored, they offer a range of services across the research pathway that will help with study feasibility, set up and delivery to time and target. Regardless of the location, study type, study size or therapy area of the research, the CRN will provide consistent and high quality support.

Whether it is help with regulatory approvals, assistance with site identification, or guidance with the costings for a study, our dedicated advisors are here to help. This infrastructure provides unparalleled access to, and understanding of, the NHS research environment. We strongly recommend that applicants familiarise themselves with the support service section of the NIHR CRN Website: http://www.nihr.ac.uk/funding-and-support/study-support-service/

Health Research Approval(s) (HRA) – Schedule(s) of Events

HRA approval is a new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with independent Research Ethics Committee (REC) opinion provided through the UK research ethics service.

It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

The following types of trial will require HRA approval:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Any clinical study where the only site is also the NHS sponsor

One aspect of HRA Approval is ensuring that there is clarity on the resource implications for participating NHS organisations and others delivering research within an NHS care setting. The documentation required for submission to the HRA enables participating NHS organisations in England to assess and confirm their capacity and capability to deliver the research.

The HRA requires a Statement(s) of Activities and **Schedule(s) of Events documents:** http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/, for each type of research site in the study. The NIHR recommend that prospective applicants use the HRA Schedule of Events document at the application stage as a tool to formulate site specific activities and to ensure consistency of format when HRA approval is required. For more information on

HRA approval, please visit the HRA website: http://www.hra.nhs.uk/

GENERAL INFORMATION

- Stage 1 applications are expected to provide an overview figure for the funds being requested. Detailed costs are required as part of stage 2 applications only; however, significant variations in the level of funds requested between stage 1 and stage 2 applications must be fully justified.
- The finance section should provide a breakdown of costs associated with undertaking the research as described in the application.
- The information entered in this section should provide an analysis of the total funds requested and should be based on current prices (an adjustment for inflation will be made annually thereafter at rates set by the Department of Health). These costs will be used to assess value for money.
- The NIHR will not support any costs incurred prior to or following the Research Award.
- It is in your best interests to undertake a thorough, realistic and accurate costing approach. For Stage 2 applications, the Selection Panel will pay close attention to any material increase in costs.
- You must provide clear and full justification for all costs; further itemisation of costs and methods of calculation may be requested to support the application at a later date.
- All applications are expected to have appropriate NHS, HEI, commercial and other partner organisation input into the finance section of the application form.
- Payments will be made to the contracted organisation only, and the contracted organisation will be responsible for passing on any money due to their partner organisation(s).
- Appropriate collaboration agreements or sub-contract agreements must be put in place for any element of the R&D cost which is to be paid to another organisation.
- Years should be calculated starting from the estimated start date of the proposed research. For example, if your project is expected to start on 1 October 2016, then its second year starts on 1 October 2017.
- If your organisation is claiming less than the maximum percentage allowed, please enter the percentage you wish to claim in the appropriate column on the application form. Please note that whilst these percentages will be used to calculate the maximum funds payable, the programme reserves the right to award for less than this maximum. Once an award has been made, the Department of Health will require the contracted organisation to provide regular (quarterly) financial statements regarding the use of funds provided under the NIHR funding scheme. The Department reserves the right to send independent auditors to the contracted organisation to confirm the actual use of funds.

Information for different types of organisation

Higher Education Institutions (HEIs)

HEIs should determine the Full Economic Costing (FEC) of their research using the Transparent Approach to Costing (TRAC) methodology. For HEIs, up to 80 percent of FEC will be paid, provided that TRAC methodology has been used.

NHS Organisations

Up to 100 percent of direct costs incurred by NHS organisations will be funded, based on costs identified through 'Attributing the costs of health and social care Research and Development' (AcoRD).

NHS indirect costs cannot be claimed through NIHR programme funding. NHS organisations are allocated NIHR Research Capability Funding (RCF) to contribute to the cost of hosting NIHR-supported research. The RCF is allocated by the Department of Health to research-active NHS organisations in receipt of NIHR income, or via NHS organisations that host local NIHR Clinical Research Networks. It will enable NHS organisations to meet some or the entire research-related component of the salary of their researchers and research support staff working on clinical and applied

health research, where that component is not already provided by another funding source. It will also contribute towards costs relating to sponsorship and governance, accommodation, financial management and human resource management.

Commercial organisations

For commercial organisations or consultancies, please fill in direct costs and commercial indirect costs. Indirect costs should be charged in proportion to the amount of research staff effort requested. Up to 100 percent of costs will be paid, on the basis that all relevant parties have agreed to the commercial terms as laid out in the NIHR standard contract.

Commercial organisation indirect costs need to demonstrate value for money. The NIHR reserves the right to set limits on indirect costs charged.

Other partner organisations

For other partner organisations (charities, Non-governmental Organisations, etc.), please fill in direct costs and other partner organisations' indirect costs. Indirect costs should be charged in proportion to the amount of research staff effort requested. Up to 100 percent of costs will be paid.

Other partner organisation indirect costs need to demonstrate value for money. The NIHR reserves the right to set limits on indirect costs charged.

APPLICATION FINANCES

The NIHR will **ONLY** fund Research Cost activities as described in AcoRD. The finance template categories the Research Costs into the following:

- Direct Costs
- Indirect Costs

1. Direct Costs

The direct costs that are specific to the research, will be charged based on the amount actually spent and that can be supported by an audit record. Only costs that can be classified as research costs can be itemised under Direct Costs. Research costs are derived from the core research activities that are being undertaken to answer the research question(s), and will end when the research ends.

Direct Costs are further categorised into the following:

- Staff Posts and Salaries & Annual Costs of Staff Posts
- Travel, subsistence and conference fees
- Equipment (including lease versus purchase costs)
- Consumables
- Patient and public involvement
- Other Direct Cost
- Patent and Legal
- Sub-contracts

Staff Posts and Salaries

This section outlines the staff salaries and relevant on-costs (i.e pay increment dates, geographic weighting, superannuation, National Insurance). Salary costs should feed into the Annual Costs of Staff Posts section of the application form.

All staff members working on the project must be listed and their annual salaries must be stated. If there are any applicants whose costs are not being claimed, you will need to state the applicants' names and explain briefly why no costs are being claimed and how their contribution will be covered.

Use current rates of pay and build in any known annual increments. Nationally or locally agreed pay increases should be excluded. Once your project has started, you will not be able to claim for pay awards retrospectively.

Annual Costs of Staff Posts
This section specifies the total annual costs of each applicant contributing to the Award. You should now allocate the individual staff member costs to each year of the Award, allowing for increments. Use current rates of pay, and build in any pay awards expected once your research is underway. Please note inflation should **NOT** be applied when calculating annual costs of staff posts.

Please note that the 'percent full time on this research' means the actual time spent on this research for the duration of employment through this project and should not be the average percentage over the whole project if a person is only employed for a certain amount of time. The 'Year' columns should reflect the actual annual costs of an individual for the research.

For example, if an individual's total annual salary costs are £20,000 and this person is expected to work 50% of their time on the research for 18 months, the 'percent full-time on this research' column should state 50 and the 'total months on this research' column should state 18. The salary costs that should be entered into the 'Year' columns are £10,000 for 'Year 1', £5,000 plus any increments for 'Year 2' and £0 for 'Year 3'.

If an individual's involvement varies over the course of the research, it may be easier to make a separate line entry each time it changes.

Please ensure that you complete the column describing the employing organisation for a member of staff as this has an impact on the level of funding provided. Staff employed by an HEI are funded at 80 percent of cost and staff employed by the NHS, commercial or other partner organisation at up to 100 percent of cost.

Shared Staff Costs
This section also includes 'Shared Staff Costs' which are located under directly allocated costs in some other funders' applications. These are a share of the costs of a resource used by an project, where the same resource is also used by other projects or activities. These are different to the Direct staff costs listed above because these costs are not exclusively related to any individual project. However, the cost of the resource still needs to be recovered, and making a fair and reasonable charge to all Awards using the resource does this. Staff such as academics and research staff (who work on more than one project) and pooled laboratory technicians should be identified in the finances as shared staff. Charge-out rates for shared staff are generally applied to researcher FTEs to derive an estimated cost for each project, and do not change during the life of the Award. Please note, HEI indirect costs cannot be claimed on shared staff, as indirect costs and estate costs are already inclusive in the charge-out rate.
Please note, the NIHR does not fund PhD studentships through its research grants (NIHR's main training opportunities can be accessed here). It is possible, however, for a researcher employed on an NIHR grant to register for a PhD studentship based on the funded project, although the NIHR will not reimburse fees.

Travel, Subsistence and Conference Fees

This section of the Financial Form includes journey costs, subsistence and conference fees.

Journey costs
Enter the total cost of transport for all journeys and the destination/purpose. If travel is by car, apply your institution's mileage rates (however, this should not exceed HMRC approved mileage allowance payments, which is 45p per mile for the first 10,000 miles and 25p thereafter). Travel by the most economic means possible is encouraged; NIHR programmes do not usually fund first class travel.

Subsistence
Subsistence covers accommodation (if necessary) and meals associated with the travel, excluding any alcoholic beverages.

Conference fees
Where national conference fees are included, a statement naming the conference, the purpose of travel and the benefit to the award must also be made; failure to adequately justify your attendance at a conference will mean the NIHR will not fund this cost.

This section includes journey costs, subsistence and conference fees. Where applicable, you will need to include the travel and subsistence costs of your steering committee, data monitoring committee and ethics committee. Travel and subsistence costs relating to dissemination should also be included here. For research of up to three years, the programme will usually fund up to a maximum of two international conference attendances (two people attending one conference or one person attending two conferences). There are no limits on the number of UK conference attendances.

Equipment

Purchase or lease costs for essential items of equipment plus maintenance and related costs not included as part of estates can be requested from the NIHR. Only purchase costs of individual pieces of equipment up to £5,000, excluding VAT, will be considered. Pieces of equipment costing more than £5,000 will usually need to be leased. Where applicants are leasing equipment with a purchase price of more than £5,000, a comparison of leasing versus purchasing costs must be provided in the 'Justification of Costs' section.

Items of equipment valued at £250 or more must be itemised separately; however, grouping the same type of equipment is permitted. Costs of computers are normally restricted to a maximum of £650 each excluding VAT. A statement of justification must be included in the relevant 'Justification of Costs' section for any purchase above this limit.

Equipment must exclude VAT, but if your organisation is unable to reclaim or recover the VAT on a piece of equipment, you should check the column 'VAT cannot be reclaimed'. You will need to seek advice from the organisation the piece of equipment is purchased from regarding its VAT status. If you check the 'VAT cannot be reclaimed' column, VAT will be calculated at 20 percent of the overall cost of that item.

Consumables

This section includes non-reusable items specific to the research. Please itemise and describe the requirements fully (e.g. postage, stationery, photocopying). These items should be research specific, not just general office costs which should be covered by indirect costs.

Patient and Public Involvement (PPI)

Please itemise and describe fully all patient and public involvement and engagement costs. This will include:

Payments for time, skills and expertise:
Offering members of the public payment for their time, skill and expertise is considered good practice in structuring and operating the proposed CRF. Rates of payment can vary and may be offered at either an hourly or daily rate. The following activities should be considered:

- Reviewing documents
- Attending meetings
- Attending training courses and conferences
- Outreach and dissemination

All out of pocket expenses should be covered. Equal opportunities for involvement are facilitated if expenses are covered. Members of the public should not end up financially worse off for providing a public service. The following expenses should be carefully considered:

- Travel (public transport, taxi fares, or an agreed private car mileage rate which includes wear and tear).
- Overnight accommodation (somewhere in the region of £100 and £150 per night).
- Subsistence (food and refreshment whilst on 'business' related to the Research, but no alcohol), somewhere in the region of £20-£30 per day.
- Childcare or replacement carer/person providing support (somewhere in the region of £100 per day).
- Costs of a Personal Carer or Support Worker of the individual's choice.
- Telephone, internet access, fax costs, stationery and other equipment – covering these costs is particularly important for members of the public who work from their own home and therefore may incur considerable costs which may be 'invisible' in organisational settings (somewhere in the region of £10 to £20 per day).
- Conference fees and training courses.

INVOLVE has produced an online cost calculator to help staff supporting research identify and calculate the costs of public involvement in their research-facing activities. It includes a guide - **Budgeting for Involvement** with step-by-step practical advice, examples and tips. The **Involvement Cost Calculator** can then be filled in and downloaded.

Other Direct Costs

These are costs, not identified elsewhere, that are specifically attributed to the research. For example, costs associated with the use of research facilities, specialist publications, open access publications, computer licensing, recruitment and advertising costs. Please note that for organisations claiming indirect/overhead costs, costs such as recruitment of staff and general training (e.g. in common IT packages) are costs that should be covered by the indirect cost element of the award being sought and should not appear in this section.

If external consultancy costs are included in this section, they must be fully justified in the 'Justification of Costs' section, specifying the hourly rate and the number of hours. Please note that consultants must not be individuals who are already employed by the applicant's institution. If they are, any costs should be entered as direct costs in the 'Details of posts and salaries' and 'Annual costs of posts' sections.

Any costs associated with publication, presentation or dissemination of findings (except related travel and subsistence or consumables costs) should be itemised and included here. Any large costs should be further detailed with a breakdown of constituent parts or a timescale profile of the costs. Meetings to share best practice, training events and events to disseminate research findings must be run at the lowest possible cost with minimal catering.

Patent and legal

The NIHR will consider supporting reasonable costs requested to protect any Intellectual Property

which arises from the research project. Any costs will be supported during the period of the research only. Supported costs include, but are not limited to, legal advice, patent and Freedom to Operate searches, patent submission costs and third-party licensing fees. The NIHR will not support any costs incurred prior to or following the research project, including patent maintenance costs. All requests should be fully itemised and justified.

Sub-contracts

A sub-contract is regarded as an external specialist service which cannot be provided by the organisation leading the project or its collaborators. Services include consultancy, design services, or the development and provision of specialist equipment. These costs can be requested for organisations providing these services in a territory that is outside England, but suitable justification is required.

2. Indirect Costs

Indirect costs are for activities or services that benefit more than the proposed Award. Their precise benefits to a specific research study are often difficult or impossible to trace.

Indirect Costs should be charged in proportion to the amount of effort requested on the Award. They comprise:

- General office and basic laboratory consumables
- Premises costs
- Library services/learning resources
- Typing/secretarial
- Finance, personnel, public relations and departmental services
- Central and distributed computing
- Charge out rates for shared equipment
- Cost of capital employed

Each organisation involved in the award should have their indirect costs individually itemised on the finance form. Please note, this is only applicable to organisations eligible to apply for indirect costs (see below for more detail).

NHS Bodies or Other Providers of NHS Services Indirect Costs

NHS Indirect Costs **cannot** be claimed through NIHR programme funding. From April 2012, NHS Bodies or other providers of NHS services have been allocated **NIHR Research Capability Funding (RCF)** to contribute to the cost of hosting NIHR-supported research. The RCF is allocated by the Department of Health to research-active NHS bodies or other providers of NHS services in receipt of NIHR income, or via NHS bodies or other providers of NHS services that host local NIHR Clinical Research Networks. It will enable NHS bodies or other providers of NHS services to meet some, or the entire research-related component of the salary of their researchers and research support staff working on clinical and applied health research, where that component is not already provided by another funding source. It will also contribute towards costs relating to sponsorship and governance, accommodation, financial management, and human resource management. For more information please click here.

Higher Education Institutions (HEIs) Indirect Costs

HEIs can claim for Indirect Costs in proportion to the amount of research staff effort (FTE) requested on the award. Individual institution Indirect Costs rates should be calculated using TRansparent Approach to Costing (TRAC) methodology. Indirect and Estates Costs should not be calculated against shared staff FTE.

Commercial/Other Partner Organisation Indirect Costs

Commercial/Other Partner Organisations can claim indirect costs which are the costs of resources used by the research that are shared by other activities. Please seek advice from your finance department about the appropriate cost for this section. It is our expectation that Commercial/Other Partner Organisation Indirect Costs show good value for money.

Commercial**/**Other Partner organisation's indirect costs need to demonstrate value for money. The NIHR reserves the right to set limits on indirect costs charged.

NHS Support, Treatment and Excess Treatment Costs

Applicants are required to provide an estimate of the patient care costs associated with the research (if applicable). An explanation of why these costs are being incurred and the basis on which the estimations have been made should be fully detailed under the relevant 'Justification of Costs' section.

Please be aware that the NIHR does not fund NHS support and/or NHS Treatment and Excess Treatment Costs. NHS support costs will be funded via the NIHR Clinical Research Networks (CRNs). NHS treatment costs, including any excess treatment costs/savings, will be met by the NHS through normal patient care commissioning arrangements.

A representative of the NHS organisation incurring any NHS support and excess treatment costs must sign off the application. The 'Declarations and signatures' page is intended to ensure that the aforementioned organisation is satisfied that all NHS support and treatment costs in the application are correct and are prepared to meet these costs.

NHS Support Costs

These are the additional patient care costs associated with the research, which would end once the R&D activity in question has stopped, even if the patient care service involved continues to be provided. These might cover items such as staff time to recruit and consent patients, or additional patient safety activities which will not form part of the on-going intervention.

Please note, the Support Cost activities (such as consenting patients) should always be attributed to NHS Support Costs regardless of whether a member of staff is employed by the NHS.

The NIHR Clinical Research Network (CRN) is responsible for funding NHS Support costs.

NIHR Clinical Research Network (CRN)

The NIHR CRN fund research support posts in the NHS, and provide training, so that researchers have access to experienced "front-line" staff, who can carry out the additional practical activities required by their study such as obtaining patient consent for participation, carrying out extra tests, and collecting the clinical data required for the research.

NIHR funded Awards are eligible for Network support, whether commercially or non-commercially sponsored, they offer a range of services across the research pathway that will help study feasibility, set up and delivery to time and target. Regardless of the location, study type, study size or therapy area of the research, they will provide consistent and high quality support.

NIHR CRN offer to researchers: http://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/

NIHR CRN Route Map: http://www.nihr.ac.uk/funding-and-support/documents/Study-Support-Service/CRN_support_routemap_2016_final.pdf

NIHR Study Support Service: http://www.nihr.ac.uk/funding-and-support/documents/Study-Support-Service/CRN_SSS_leaflet_Sept16_forweb.pdf

NHS Treatment and Excess Treatment Costs

These are the patient care costs that would continue to be incurred if the patient care service in question continued to be provided after the R&D activity has stopped. In determining NHS treatment costs you must assume that the patient care service being assessed will continue even though there may be no plans for it to do so.

Where patient care is being provided which differs from the normal standard treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given), the difference between the total treatment costs and the costs of the usual standard care (if any) constitutes excess treatment cost/saving, but is nonetheless part of the treatment cost, not an NHS support or research cost. These costs should be determined in conjunction with your NHS trust partner(s) and their commissioners.

Please note, if the patient care intervention under investigation is in addition to usual care, there is no need to complete the 'usual treatment costs' section, however, this will need to be justified in the relevant 'justification of costs' section. If the patient care intervention under investigation either wholly or partially replaces usual care, the 'usual treatment costs' section must be completed.

Please note, for Awards that are testing patient care interventions in a ***Phase 1*** or a ***First in Man*** trial (i.e. the first time intervention has been tested on patients/healthy volunteers, small patient sample sizes, focused on the safety rather than efficacy of the patient care intervention), the costs relating to manufacturing the patient care intervention at this stage should be attributed to Research Costs. However, the delivery of the intervention should follow the normal attribution process, i.e. NHS Treatment Costs. In contrast, Awards testing patient care interventions in a ***Pilot*** or ***Feasibility*** trial, the costs relating to both manufacturing and delivery of the patient care intervention at this stage should be attributed to NHS Treatment Costs.

NHS England

Research is an important core activity of the NHS that NHS England is keen to promote and support in line with its statutory responsibility. It also has a responsibility to ensure that the treatment costs of patients, involved in non-commercial research, funded by the Government and research charities, are met.

NHS England has been working in consultation with Department of Health (DH) and other key stakeholders to develop an NHS England strategic plan on the process and funding of Excess Treatment Costs that delivers DH policy. As a result, NHS England has published new guidance to help clarify the rules and expectations: https://www.england.nhs.uk/ourwork/research/etc/

Justification of Costs

Please describe how your application provides value for money by providing a breakdown of and justification for all costs and describing how they will contribute to the project. Please also provide a breakdown of the NHS costs associated with undertaking the research and provide justification for the resources required. If there are no NHS support costs or excess treatment costs associated with the research, you must explain why this is the case. You should also indicate here how your research will potentially benefit the NHS (likely cost savings, treatment times, etc.)

Appendix 2: Patient and Public involvement (PPI)

Plain English Summary

The Department of Health and the NIHR support the inclusion of the public in all stages of the R&D process, including commissioning, and the i4i programme puts very strong emphasis on the importance of R&D that can demonstrate impact for patients. It is therefore essential that you make the content of your application and the implications of your project evident to members of commissioning boards and reviewers.

A plain English summary is a clear explanation of your research; it is not the same as a scientific abstract. Many reviewers use this summary to inform their review of your funding application. They include clinicians and researchers who do not have specialist knowledge of your field as well as members of the public. If your application for funding is successful, the summary will be used on the NIHR and other websites.

A good quality plain English summary providing an easy to read overview of your whole study will help:

- those carrying out the review (reviewers and board and panel members) to have a better understanding of your research proposal
- inform others about your research, such as members of the public, health professionals, policy makers and the media
- the research funders to publicise the research they fund

Your plain English summary must not exceed 300 words and should include the aim(s) of the research, the background to the research, the design and methods used, patient and public involvement and dissemination. It may be helpful to involve patients, carers or members of the public in developing a plain English summary.

Further guidance on writing in plain English is available online at NIHR Make it clear. You may also contact your local Research Design Service for further help.

If we feel that your plain English summary is not clear and of a good quality, then you may be required to amend your summary prior to final funding approval. The plain English summary of funded projects will also be published on the i4i website, so please ensure that it does not contain any commercially sensitive information.

PPI Resources

There are a number of organisations who may be able to provide useful resources, advice and support on patient and public involvement in research.

The Research Design Service (RDS) provides advice and support to researchers developing research proposals for submission to the NIHR and other national funding organisations for health and social care research.

INVOLVE provide advice and a range of resources on patient and public involvement in research, including:

- invoDIRECT, a directory of research networks and organisations supporting involvement
- Resources which include briefing notes for researchers on what public involvement is and how to involve people in research

- An involvement cost calculator to help with budgeting
- Searchable databases including an evidence library and many other resources
- People in Research, a website with information for patients and the public about current opportunities for getting involved in research; researchers and funders can use People in Research to advertise and invite patients and the public to get involved in their research

The James Lind Alliance (JLA) provides step-by-step guidance on involving patients and clinicians in the identification and prioritisation of research topics and questions.

More information on patient and public involvement in NIHR research can be found here.

Patients, service users or carers as co-applicants

We recognise and value the varied perspectives that patients, service users and carers can bring to research as co-applicants. Any such co-applicants are not required to provide a formal CV. However, in a separate supporting document, they are required to provide a brief summary of their knowledge, skills and experience relevant to their involvement in the research.

This could include information about:

- Previous or present work, whether paid or unpaid, with any relevant organisations
- Links with any relevant groups, committees, networks or organisations
- Experience of particular health conditions, treatments, use of services or as a member of a particular community
- Knowledge and experience of research including previous research undertaken
- Knowledge and experience of patient and public involvement including previous involvement activities
- Skills from any other roles that are transferable
- Relevant qualifications, training and learning