

## **NIHR INVENTION FOR INNOVATION PROGRAMME**

### **Future Product Development Funding Stream 3a**

#### **Guidance Information for Applications**

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## Invention for Innovation (i4i)

The Invention for Innovation (i4i) programme is one of a new generation of research programmes to be supported through the National Institute for Health Research (NIHR), as outlined in the Department of Health's research strategy *Best Research for Best Health (2006)*. Please see the following link for further information: [www.nihr.ac.uk/files/pdfs/Implementation\\_Plan\\_6.4\\_Invention\\_for\\_Innovation\\_August\\_2007.pdf](http://www.nihr.ac.uk/files/pdfs/Implementation_Plan_6.4_Invention_for_Innovation_August_2007.pdf).

The i4i programme aims to improve the speed with which inventions can be turned into new products that the health services require to meet the demands of the 21<sup>st</sup> Century. The programme also aims to streamline the innovation process, whilst creating strong links with the invention or "ideas generation" community and working with those organisations which can support commercialisation and exploitation of the new products developed.

Activities funded under the i4i programme include:

- Future Product Development (FPD);
- Small Business Research Initiative (SBRI);
- Pilot Healthcare Technology Co-operatives (HTCs);
- Challenge Fund for Innovation (CFI) supporting:
  - NIHR involvement in Assisted Living Innovation Platform
  - NIHR involvement in Knowledge Transfer Partnership programme
  - NIHR involvement with Medical Futures
  - NIHR involvement in MATCH PLUS project

The i4i programme will stimulate the flow of new product ideas into the market. The FPD activity follows on from the successful funding streams of NEAT and HTD, and will aim to simplify the procedure for transition between the three stages by providing support for successful projects, as well as improving links to other organisations and activities across the innovation landscape by investing in them through the CFI.

## **i4i Future Product Development Funding Opportunities**

The i4i Future Product Development funding stream consists of four components:

### **1) Future Product Development Stream 1 (FPD1) – Feasibility study**

Lasting a maximum of 1 year, academic-led investigation to determine whether a piece of prior basic research or an existing technology can be used to meet a healthcare need. There should be the potential for a medical device, based on the technology or technologies, to be developed through further applied R&D. Funding up to £100K is available.

### **2) Future Product Development Stream 2 (FPD2) – Applied research project**

A more detailed academic-led study building on the results of a completed assessment of the feasibility, to provide further evidence of the capability to deliver improved healthcare outcomes, of technical progress and of commercial opportunities. Funding of £150K per year is typically available.

### **3) Future Product Development Stream 3a (FPD3a) – Commercial viability assessment**

Lasting a maximum of 1 year, collaboration between at least one industry and one research (academic or clinical) partner to determine the commercial viability of a proposed device or technology, with the development of a robust route to market and a strong, appropriate consortia being the main deliverables. Serving primarily as the first stage of a full collaborative applied research project, costs can be no more than £100K in total, and 75% funding is available.

### **4) Future Product Development Stream 3b (FPD3b) – Collaborative applied research**

Involving collaborations between industry and research partners, a more detailed study building on the results of a completed assessment of the feasibility and commercial viability, aimed to provide further evidence of the capability to deliver improved healthcare outcomes, of technical progress and of commercial opportunities. Funding to a maximum of 50% of the total project costs, with typically £200K of funding awarded per annum.

**Applications can be made to any of the above four funding streams. This guidance document deals with the FPD3a funding stream only. Guidance documents for the other funding streams are available from the i4i website.**

## Eligibility

The FPD3a funding stream is directed towards collaborative research into innovative healthcare technologies which are focussed towards the development of new and commercially viable medical devices or related products that address an existing or emerging healthcare need. Collaboration is likely to embrace industry, academia and NHS clinicians. At a minimum, teams must contain at least one industrial collaborator and one UK research-based collaborator. The involvement of patients or their representatives is desirable.

The FPD3a funding stream covers projects which are developing:

- medical devices falling within the scope of the EU Medical Devices Directives;
- other products used in the NHS which are accessories to medical devices (e.g. cleaner/sterilisers) or are closely related to them;
- novel information technology that enables a significant improvement in the performance of healthcare technologies.

The funding stream **does not fund**:

- any project where the primary intended action of the product, in or on the human body, is pharmacological, immunological or metabolic;
- innovation or knowledge networks and healthcare technology cooperatives which aim to accelerate the development of innovative technology products;
- hospital information systems and related software;
- stand-alone software; however, if the software is integral to a device, this may be acceptable;
- assessments or clinical trials of fully developed products or interventions that are already in use within the NHS;
- studies which examine the impact of interventions on service delivery and organisation;
- professional training.

**An FPD3a study is not a self-contained project in its own right but should represent the first stage of wider applied R&D ultimately leading to the development of a new healthcare product.**

## **Project Assessment Criteria**

All applications for funding under the i4i programme's Future Product Development funding stream will be judged on the following four criteria; whilst it may not be possible to answer these questions within an FPD3a application, project teams will need to explain how they will be addressed.

### **Criterion 1**

#### **There needs to be strong evidence of clinical or healthcare need with high relevance to the NHS**

- a. What is the clinical need for the proposed device/technology within the NHS and globally?
- b. What value, in terms of estimated cost and benefit, does the proposed device/technology provide to both the NHS and patients?
- c. How will clinical practice be affected by using the device and will this lead to constraints in adoption?
- d. How will the proposed device/technology address healthcare priorities within the NHS?
- e. Are users and patients or their representative associations likely to welcome the new device/technology?

### **Criterion 2**

#### **There must be innovation and a potential to generate and exploit intellectual property**

- f. What is innovative about the proposed device/technology and what advance is there over current science and technology?
- g. What are the competitor devices, clinical practices and technologies and how strong is the market competition? How will the competition react to the introduction of the new medical device? Is there freedom to operate in this area?
- h. Have you completed a search for existing intellectual property? What intellectual property will be generated, and how will this be identified and managed?

### **Criterion 3**

#### **There needs to be a clear and accessible route to market and identifiable capacity to develop applications and exploit them**

- i. What are the potential applications of the project and how do you intend to disseminate and exploit the results?
- j. What are the market opportunities, both domestic and global, and the expected impact of the proposed device/technology?
- k. What are the regulatory barriers for the device/technology for entry into the target markets? Is animal and/or clinical testing required before regulatory approval is obtained?
- l. What are the key stages and challenges on the route to market?

#### **Criterion 4**

##### **The project team and project plan need to be appropriate for the scale and complexity of the project**

- m. What are the aims of the proposed project?
- n. Does the research consortium have the right skills and experience to deliver the identifiable benefits?
- o. How will patient's/user representatives contribute to the project?
- p. What are the main technical barriers to successful completion of the project?
- q. How will the project be managed?
- r. What are the key risks to successful completion of the project? What steps have been taken to mitigate these?

**The primary objective of an FPD3a project should be to determine whether the innovative use of an existing or emerging product or technology can be used to meet a healthcare need, and to identify the technical barriers that need to be overcome. Deliverables are also expected to include an analysis of the clinical need, a robust plan for commercialisation as well as the formation of a strong consortium to take the commercialisation plan forward.**

In addition, it will be expected that the following general principles are adhered to for an i4i FPD3a project:

- Fit within the overall scope and aim of an i4i and the Future Product Development funding stream.
- Have ethical approval if this is appropriate.
- Adhere to the research governance framework (see link below):

[www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/Researchgovernance/index.htm](http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/Researchgovernance/index.htm)

#### **Funding Limits and Duration**

The maximum duration for an FPD3a project is 12 months with maximum project costs of £100K, with grants awarded to a maximum of 75% of the project costs. Each FPD3a project is likely to be followed by an FPD3b project, although this is not essential. It is intended that any proposal to continue to FPD3b will be considered before the end of the FPD3a project in order to minimise any gaps in funding. The programme will fund 80% of the FEC of research in HEIs, as calculated using the transparent approach to costing (TRAC) methodology. For NHS organisations, costs relating to management, patent searching, market assessments and economic viability of the ultimate product may be included. Excess service costs incurred by NHS providers will not normally be funded. Further information can be found below in the **Eligible Costs** section.

## **Eligible Costs**

The eligible costs for each collaborator that can be included in the calculation of the total project cost are those that are directly attributable to the project, and can include:

- salaries of personnel working directly on the project;
- materials consumed in the course of the project;
- capital equipment purchased or constructed for the project, less the estimated value to the business of the equipment at the end of the project;
- sub-contract charges and consultancy fees, fees for trials and testing and preparation of technical manuals;
- project manager costs (travel, etc.) that are additional to those normally involved;
- training that is specific to the project;
- reasonable licensing fees paid to third parties for acquiring new technology;
- reasonable patenting costs, where this would otherwise fall on small firms;
- an allowance for overheads (to be supported by a breakdown and justification and limited to a maximum of 46% for universities).

Costs that are not eligible are:

- market research and product launch activities;
- interest, hire purchase interest, and any associated service charges arising from hire purchase, bad debts, and marketing costs;
- profit earned by a subsidiary or an associate company on work sub-contracted under the project;
- inflation and contingency allowances expressed as an arbitrary % addition to eligible costs (however, can include realistic estimates of likely rise in labour costs and foreseen increases on specific materials);
- input VAT (defined as the charge made on goods and services purchased for business purposes by taxable persons).

Day rates will need to be justified, and the sponsors may wish to negotiate project costs and day rates before approving the project for funding.

## **Overheads**

Overheads for industrial collaborators are not limited to a fixed percentage, but require justification and are dealt with on a case by case basis.

## **Full Economic Costing**

The Department of Health fully supports the Government's desire to move the UK's research base to a long-term sustainable footing. Academic Collaborators (Universities and Higher Education Institutions (HEIs)) should determine the Full Economic Cost (FEC) of their research using the Transparent Approach  
FPD3a Guidance Version 2, July 2009

to Costing (TRAC) methodology. For universities and HEIs, 80% of FEC will be paid, provided that TRAC methodology has been used.

Under Full Economic Costing, there are 4 main categories of cost:

1. Directly Incurred Costs
2. Directly Allocated Costs
3. Indirect Costs
4. Exceptional Costs

### **1. Directly Incurred Costs:**

These are costs that are specific to the project, which will be charged to the project as the amount actually spent and can be supported by an audit record. They comprise:

- Labour costs for all those contributing to the project, including normal salary increments and increased costs arising from salary awards, broken down by individual;
- Essential items of equipment (items over £3000 should be listed individually) plus maintenance and related costs that are not included as part of estates. These can be rented or purchase costs;
- Travel and subsistence;
- Consumables specific to the project;
- Patent and legal costs;
- Other costs specifically attributed to the project, including externally provided specialist services such as laboratory tests, x-rays or work sub-contracted out from the research group.

Note: should the non-staff costs exceed £50,000, please list items up to a total of £50,000 separately in this section. Costs exceeding £50,000 may be considered exceptional and should be entered into the Exceptional Costs table. For example, total equipment costs of £51,000 would be entered as £50,000 in the Directly Incurred Costs table and £1,000 in the Exceptional Costs table. The first £50,000 will be funded at 80%.

Costs in excess of £50,000 are likely to be funded at 100%.

### **2. Directly Allocated Costs**

These are costs that would still be incurred by your institution if the proposed research did not go ahead, and are the costs of an institution's research resources that will be charged to the project on the basis of estimated use, rather than actual costs. They comprise:

- Investigator's costs, unless directly incurred or non-chargeable
- Costs of pooled staff effort

- Estates costs which include building and premises costs, basic services and utilities, lease/rent/rates, insurance, cleaning/portering/security/safety, staff facilities, any clerical staff and equipment maintenance not included as directly incurred costs
- Usage costs of major research facilities
- Central and distributed computing
- Charge out rates for shared equipment

### **3. Indirect Costs**

Indirect costs will be charged in proportion to the amount of research staff effort requested on the grant. Institutions will calculate them using their own cost rates and TRAC methodology. They comprise:

- General office and basic laboratory consumables
- Library services/learning resources
- Typing/secretarial
- Finance, personnel, public relations and departmental services
- Central and distributed computing if not directly allocated
- Cost of capital employed

### **4. Exceptional Costs**

Exceptional Costs are directly incurred non-staff costs in excess of £50,000 (see note under Directly Incurred Costs section). Exceptional costs are likely to be funded at a rate of 100%.

## **Programme Management**

All funded projects will be managed and monitored via the submission of quarterly project reports and statements of expenditure. These are augmented by project visits every six months from a member of the Advisory Committee and one of the Programme Managers.

## Project Selection

Applying to FPD3a is a single **stage process** and does not involve an independent peer review process. Applications for FPD3 funding will be judged initially on their fit to the scope of the programme by the i4i secretariat supported by appropriate members of the Programme Advisory Committee. The scientific content of applications which fit the scope of the initiative will then be considered by the full Programme Advisory Committee and judged upon the criteria outlined within the Project Assessment Criteria. The Expert Panel's decision will be final and appeals considered only in exceptional circumstances. Reasons for rejection will be given to researchers submitting proposals.

The standard contract, giving oversight and payment details and outlining specific requirements will be available to download via the i4i website: [www.nihr-ccf.org.uk/site/programmes/i4i/](http://www.nihr-ccf.org.uk/site/programmes/i4i/)

All intellectual property will be retained by the contractor and its collaborators, who will be expected to protect and exploit it effectively. The policy framework for the management of intellectual property within the NHS is outlined on the Department of Health website at:

[www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/DH\\_4002178](http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/DH_4002178).

One of the aims of i4i is to enable projects to begin as quickly as possible once approved. Delays often occur with the signing of collaboration agreements; therefore, a signed Declaration will be requested to accompany full proposals submitted, as well as a draft copy of the proposed collaboration agreement. **Prior to applying for funding, it is requested the applicant consider the details of the downloadable contract and can be confident that delays in signing will not occur if funding is offered. If, for reasons other than exceptional circumstances, the actions of the applicant cause delays of greater than six months, the Department of Health maintains the right to withdraw the funding offer.**

## Application process

The names and affiliations of the Programme Advisory Committee will be listed on the i4i website, along with their full affiliations. All members of the Committee as well as independent peer reviewers are required to sign a confidentiality agreement to protect any commercially sensitive information within the applications.

The application process for the i4i programme will be managed through the secure area (extranet) of the Central Commissioning Facility website. **Applications will only be accepted when received through this route.** Applications received by email, post or any means other than the website will not be accepted. In order to submit an application to the i4i programme, you must firstly register with the CCF website at [www.nihr-ccf.org.uk/site/registration](http://www.nihr-ccf.org.uk/site/registration). For instructions on how to obtain and submit your application form from the website, please see Annex 1.

Applicants should note that the full application will be read by all members of the PMC. The use of plain English with the minimum of acronyms and technical terms is encouraged.

## Guidance on completing the application form

These notes should be read in conjunction with the application form and are designed to help you to provide the information required. **Where text limits are indicated, please do not exceed these, as this will result in your application being rejected.**

In order for your application to be accepted you must submit the minimal required information. This information includes all mandatory fields from the application form and failure to complete the form's mandatory fields will result in your application being rejected on the grounds that it is incomplete. **All mandatory fields are identified by an asterisk (\*).**

### Reference number

This is the reference number of your application and it should be noted that you will need it for all subsequent enquiries. If your application is successful, this reference number will stay with the project for its duration.

The reference number is not filled in by the applicant; it should already be present when the form is downloaded. Please contact the Central Commissioning Facility if your application does not have a reference number.

### 1. Application

#### Short Project Title (Mandatory)

Please provide the title for the project. This should be both clearly descriptive and concise.

### **Keywords**

Please provide a short list of the most relevant keywords for the proposed project. These will be used to ensure it is reviewed by the most relevant individuals.

### **Project duration (Mandatory)**

Please indicate the expected length of the proposed project in months. Project Grants can be up to 36 months in length.

### **Total project cost and total funding requested (Mandatory)**

Project grants should be up to 12 months in duration with a **maximum total cost of £100k and up to 75% available as funding**. It is intended that this sum will meet all directly incurred costs which research providers incur. It will fund 80% of the FEC of research in Higher Education Institutions (HEIs), as calculated using the transparent approach to costing (TRAC) methodology. For HEIs, the total funding requested cost on the application form should be the 80% FEC value. For NHS organisations, costs relating to management, patent searching, market assessments and economic viability of the ultimate product may be included (please see the Eligible Costs section for more details). Industrial partners may request a maximum of 50% of their project costs covered within an FPD3 grant but must ensure that the prerequisite matched funding is provided.

**Support costs and treatment costs (including excess treatment costs) are not funded through this programme. These costs should be met through normal patient care commissioning arrangements.**

### **2. Lead applicant's details (Mandatory)**

Please submit the lead applicant's name, post held, department, project role and percentage of time to be spent on the project.

### **3. Contact details (Mandatory)**

Please submit the address and contact details as required; all boxes marked with an asterisk are mandatory. In addition, please provide details of where you heard about the programme.

### **4. Collaborators**

Please submit the names, addresses and contact details of all co-applicants. Give an outline of the role each member of the research team will play in the project on a day-to-day basis. The amount of time to be spent working on the project either as a percentage or proportion of a full time equivalent (FTE) can be entered into the finance forms.

## **5. Synopsis (Mandatory)**

Provide a structured abstract which outlines the background to the research project, the aims of the work; including the question to be addressed by this research, the plan of investigation and the desired outcome including its impact on the NHS and how the results may affect treatment of patients. The abstract should summarise the potential benefits to the patient and the NHS. Please observe the text limits for each section of the abstract.

## **6. Executive summary (Mandatory)**

The Department of Health and the National Institute for Health Research support the inclusion of the public in all stages of the research process, including commissioning, and the i4i programme puts very strong emphasis on the importance of projects that can demonstrate impact for patients. It is essential, therefore, that you make the content of your application and the implications of your research evident to lay members of commissioning boards. Please provide a plain English version of the scientific summary, covering all key points and avoiding technical terms which can be understood by non-technical individuals.

## **7. Clinical Need and Relevance to the NHS (Mandatory)**

Please indicate the clinical need of the proposed device/technology and its relevance to both the NHS and global markets, referring to Criterion 1 of the Project Assessment Criteria. Questions that should be addressed include the following.

- What is the clinical problem being addressed?
- What is the clinical need, both domestically and globally?
- How will the proposed device/technology address current healthcare priorities within the NHS?
- What are the shortcomings of existing clinical techniques and technologies?
- How will the proposed device satisfy both the clinical need and the shortcomings of the current state-of-the-art?

## **8. Innovation and Intellectual Property (Mandatory)**

Please outline the innovation of the proposed device/technology, and the potential to generate and exploit intellectual property, referring to Criterion 2 of the Project Assessment Criteria. Questions which should be addressed include the following.

- What is the function of the proposed technology and what is the advance over current science and technology?
- What are the competitor devices, clinical practices and technologies?
- What are the benefits of the proposed technology over current practices?
- What relevant IP exists which is owned by the applicant(s)?

- Has a search for existing IP been conducted? What related or similar IP exists and is there similar or related work being carried out?

### **9. Development and Exploitation (Mandatory)**

If successful please indicate your plans for disseminating the findings of this project. In addition, also indicate how the project could be taken further and how any IPR generated could be exploited, referring to Criterion 3 of the Project Assessment Criteria. Questions which should be answered include the following.

- What are the target applications for the project and how do you intend to disseminate and exploit the results?
- What is the current cost of the clinical problem to the NHS?
- What are the market opportunities both in the UK and worldwide and how will they be addressed?
- Which organisation will sell the product?
- What is the target selling price of the device, as well as the target volume?
- What regulatory approvals are required for the device/technology?

### **10. Aims of the project (Mandatory)**

Projects in this programme will vary considerably in their research design; however, this section of the form should be used to indicate the main aims of the project, outlining the research question which the work will address and the technical issues to be addressed and overcome. Three points highlighting the key measures of success should also be included.

### **11. Key Risks and Technical Challenges (Mandatory)**

Please outline the key risks and challenges to successful completion of the project and how they might be mitigated.

### **12. Project plan and methodology (Mandatory)**

The project plan should be separated into distinct packages each of which identifies well-defined milestones and deliverables. It is often useful to include a Gantt chart which can be supplied in Annex 3. An indication of how any IPR which arose during the project would be handled should be provided.

Please refer to the project assessment criteria on page 3.

### **13-14. Public involvement (Mandatory)**

It is anticipated that for many, although not all projects, there will be a particularly significant component of public involvement and it is important that this is described clearly, using the definitions offered. For further information about active public involvement, please see Appendix 2, which has been written in close co-operation with INVOLVE.

### **15. Project management (Mandatory)**

Identify the project management processes that will ensure that milestones are achieved in a timely manner. This should include information pertaining to the schedule of meetings for the project group to permit evaluation of progress and dissemination. Highlight the role of any advisory or reference groups associated with the project.

### **16. Justification of costs (Mandatory)**

In this section an explanation of the role of individual members of the research team and the rationale for their inclusion should be provided (See also Section 21, Annex 2). There is no need to comment on every item of costs, but there should be comment on major sources of expenditure.

### **17. Ethical approval (Mandatory)**

Please provide details of whether the project involves clinical testing and/or testing on animals. If it does, you must send information about who will be responsible for managing and obtaining the appropriate ethical and regulatory approval.

### **18. Declaration concerning other applications (Mandatory)**

In this section, you should provide us the details of any pending and previous funding applications that have been made for this project. This should include HTD/FPD3, NEAT/FPD1/FPD2, and other sources such as EPSRC. Please note that, if the project has been previously funded under FPD1 or FPD2, we will make every effort to ensure your application progresses as quickly as possible.

### **19. Monitoring information (Mandatory)**

Please use the drop-down menus to provide the information requested. This will be used by the Department of Health and the National Institute for Health Research for accountability, audit and monitoring purposes.

### **20. Application finances (Mandatory)**

Please provide a breakdown of costs associated with undertaking the project described **on the spreadsheet provided. A separate sheet must be completed for each partner.**

For Universities and HEIs, 80% of FECs will be paid, provided that TRAC (transparent approach to costing) methodology has been used. For NHS organisations, 100% of directly incurred and directly allocated costs, excluding estate costs will be payable. Costs should cover the following, as applicable:

#### **Directly incurred costs:**

These are costs that are specific to the project that will be charged to the project as the amount actually spent and can be supported by an audit record. They comprise:

- labour costs for all those contributing to the project, including normal salary increments and increased costs arising from salary awards, broken down by individual
- essential items of equipment (items over £1000 should be listed individually) plus maintenance and related costs that are not included as part of estates
- travel and subsistence
- consumables specific to the project
- externally provided specialist services such as laboratory tests, x-rays or work sub-contracted out from the research group
- other costs specifically attributed to the project.

### **Directly allocated costs**

These are the costs of an institution's research resources that will be charged to the project on the basis of estimated use, rather than actual costs. They comprise:

- Investigators costs, unless directly incurred or non-chargeable
- Costs of pooled staff effort
- Estates costs (building and premises costs, basic services and utilities, lease/rent/rates, insurance, cleaning/portering/security/safety, staff facilities, any clerical staff and equipment maintenance not included as directly incurred costs)
- Usage costs of major research facilities
- Central and distributed computing
- Charge out rates for shared equipment.

### **Indirect costs**

Indirect costs will be charged in proportion to the amount of research staff effort requested on the grant. Institutions will calculate them, using their own cost rates. They comprise:

- General office and basic laboratory consumables
- Library services/learning resources
- Typing/secretarial
- Finance, personnel, public relations and departmental services
- Central and distributed computing if not directly allocated
- Cost of capital employed.

Itemisation of costs and methods of calculation may be requested to support the application at a later date.

The information entered here should provide an analysis of the total funds requested based on current prices. These costings will be used to assess value for money. Total grant value, including annual inflationary up-lift(s), should be included. The Department of Health will meet costs of nationally or locally agreed pay increases (but not re-grading).

#### **20a and 20b. Declarations and signatures (Mandatory)**

Applicants are expected, before submitting applications, to have discussed their proposals with their own and other bodies whose co-operation will be required in the conduct of the project. In order to assure us that there is full cooperation from all partners within the consortium, each institution involved in the project will need to send us a copy of the declarations and signatures form associated with the application form. These must be include being signed by an administrative or finance officer for the each partner to confirm that the financial details of the application are correct and that the host institution will agree to administer the award if made, as well as the commercial partners agreeing to the proposed undertaking. Please note that this does not replace a formal collaboration agreement, a draft of which will need to be appended to the application. The declarations form should be printed, signed by the relevant authority and returned by post to the i4i Secretariat at the address below. **Please do not send completed applications by post.**

**Quotec Ltd  
The Dray House  
The Maltings  
School Lane  
Amersham  
HP7 0ET**

**Failure to submit your correctly completed declarations and signatures form by the deadline will result in your application being rejected on the grounds that it is incomplete.**

**Any queries should be directed to the following [i4i.programme@nihr-ccf.org.uk](mailto:i4i.programme@nihr-ccf.org.uk) or Tel: 01494 432277**

**NOTE: Please ensure that you place “FPD3a” in the subject box of any email sent to the NIHR CCF.**

**21. Other information to be submitted with the application form. Please note there are 5 mandatory documents required to support your application, outlined below.**

- **The application finance forms (mandatory):** Please see point 20 for details.
- **Annex 1 (mandatory):** Should consist of one-page Curriculum Vitae from each applicant, list of current grants, research commitments and publications relating to this application\*.

- **Annex 2 (mandatory):** Must contain a detailed work programme\*, consisting of two sections: the research methodology and work package descriptions.

*Section 1 Research Methodology* - Please use this section to provide further details on the research programme and methodology that will be used in your project, taking care to identify and justify the scale of each activity e.g. the number of patients in clinical trials and the calculations used to determine those numbers. Also include a risk assessment identifying the most risky elements of the project and explain how you propose to manage the risks.

*Section 2 Work Package Descriptions* – Please provide summary information for each work package using the format in the example below:

<b>Work Package 1</b>	<b>Hydrodynamic performance of a model device</b>		
<b>Start date</b>	Month 4		
<b>Objective</b>	Investigate the hydrodynamic performance of the model prototype device		
<b>Description of work</b>	Size 23 mm prototype device P1 manufactured with the model material will be studied under steady and pulsatile flows, to obtain hydraulic performance parameters.		
<b>People Required</b>	<b>Scale</b>	<b>Days</b>	<b>Estimated Cost</b>
	RA (Collaborator 1)	36	£11946
	RA (Collaborator 2)	18	£6217
	Technologist (Collaborator 1)	28	£5729
	Sub-Total		£23892
<b>Consumables</b>	Collaborator 1		£1000
	Collaborator 2		£500
	Sub-Total		£1500
<b>Capital Items</b>			£0
<b>Total Cost</b>			<b>£25392</b>
<b>Deliverable</b>	Evaluated model prototype device		
<b>Target Completion Date</b>	Month 9		

- **Annex 3 (mandatory):** Gantt chart indicating a schedule for the completion of work packages\*.
- **Annex 4 (mandatory):** draft collaboration agreement\*.

- **Annex 5:** Supporting documentation including diagrams, pictures, questionnaires and letters of support (File size should not exceed 5Mb). The main application can cross-refer to any material here, but care should be taken that the application is as full as possible in its own right.

**Annexes are not downloaded from the website.** Annexes 1-5 should be files generated by the applicant and named as follows: annex1\_filename; annex2\_filename *etc.* For example, annex 1 for application II-3A-0809-10001 should be named annex1\_ II-3A-0809-10001.

Please refer to Appendix 1 for instructions on how to download and name the finance forms.

**For each annex you will be permitted to upload one file; therefore, if you have multiple documents they must be combined into one file for upload.** Files with the following extension will be accepted: .xls .doc .ppt .pdf and .mpp

## Appendix 1

### Using the website

#### The Application form

##### Downloading and uploading your application

The application process for the i4i programme is an electronic application process which will be managed through the NIHR Central Commissioning Facility website. You will be asked to download the application and finance form, you can then complete them offline and upload your completed forms through the website.

**PLEASE NOTE: Microsoft Word and Excel 2007 file formats are currently not supported and cannot be uploaded to this website. If using Microsoft Word or Excel 2007, please use the "save as" command and save the application form as a Word 97-2003 document and the finance form(s) as an Excel 97-2003 workbook. This also applies to any documents submitted as an annex.**

##### Downloading your forms

Please ensure that the forms are downloaded and uploaded using the registration of the lead applicant. If you are a co-applicant or PA of the lead applicant, please register in the lead applicant's name or you will be assigned as the lead applicant on this application.

- Log in to the CCF website at [www.nihr-ccf.org.uk/extranet/](http://www.nihr-ccf.org.uk/extranet/) with your username (Email address) and password
- Click on the "i4i" link in the left hand menu
- Click on the "FPD3a Funding Stream Apply" link in the left hand menu
- Click on the "Download and Submit" button
- Click on the "Begin Download" button
- Click the "Download" button and confirm your download, saving the application form to your local drive
- Click the "Download" button and confirm your download, saving the finance form to your local drive
- To submit more than one application, you must click on the "New Project" button. Each new application will be assigned a unique reference number which should be noted.

If you require multiple finance forms, please save a copy of the finance form and rename it.

For example, you will download a form called:

Finform\_ II-3A-0809-10001. If an additional form is required then it should be labelled as Finform\_part01\_II-3A-0809-10001. Please note that part01 is the variable portion. A second additional form would be labelled part02 etc.

## Your reference number

This is the reference number of your application and you should note this number as you will need it for all subsequent enquiries. If your application is successful, this reference number will stay with the project for its lifetime.

The reference number is not filled in by the applicant; it should already be present when the form is downloaded. Please contact the Central Commissioning Facility if your application does not have a reference number.

## Uploading your application forms

After completing your application, please log in to the website at [www.nihr-ccf.org.uk/extranet/](http://www.nihr-ccf.org.uk/extranet/)

- Click on the “i4i” link in the left hand menu
- Click on the “FPD3a Funding Stream Apply” link in the left hand menu
- Click on the “Download and Submit” button
- Click on the “Begin Submit” button. You will be given the option to submit all the mandatory files and two optional files, each file is submitted sequentially
- You must click the “Submit” buttons individually for each file and use the browse button to locate the file on your local network/drive
- You will then be asked to confirm your submission
- Please note that your application form is numbered with your reference number. **The document you upload must have the same file name as that downloaded from the website. Failure to submit a file with the same name will result in the upload being rejected.**
- The finance form template must be named correctly and submitted by the lead applicant (e.g. Finform\_II-3A-0809-10001).
- Once you have uploaded all the required files you will see a green tick appear on the submission page.
- **Please note:** It is possible to overwrite any files up to the submission deadline.

On completion of your submission you will receive an email thanking you for your submission. Please keep this email as proof of submission. **If you do not receive this email within 24 hours of completing the submission, please contact the CCF.**

**Please note that during busy periods such as close to a competition deadline it will take slightly longer to upload your application. During this time our helpline will be receiving a very high volume of calls. We therefore advise that you do not leave your submission until the last 24 hours of the competition.**

Common issues when uploading:

- Please note that if you wish to upload a file, you must have the associated software on your PC to open that file. For example, to upload an .xls file you must have excel on your PC.
- Please ensure that the file you are trying to upload is closed otherwise you will get an error message and the file will not upload properly.
- If you have uploaded the wrong version of the document, you can overwrite it by uploading the correct document again. You will be permitted to overwrite the documents up until the submission deadline.
- If you encounter problems when uploading the forms this may be because of the Internet browser you are using. Some applicants that use Firefox have encountered problems when uploading the finance form. If this occurs please try with Internet Explorer or Netscape; alternatively contact the CCF helpline for assistance on 020 8943 8990.

## Appendix 2

# RESOURCES FOR GRANT APPLICANTS ABOUT INVOLVING THE PUBLIC IN RESEARCH

## 1) INVOLVE ([www.invo.org.uk](http://www.invo.org.uk))

INVOLVE is a national advisory group funded by the National Institute for Health Research, which aims to promote and support active public involvement in NHS, public health and social care research. INVOLVE was established to promote public involvement in research, in order to improve the way that research is prioritised, commissioned, undertaken, communicated and used. INVOLVE believe that the active involvement of the public in the research process leads to research that is more relevant to people and is more likely to be used. Research which reflects the needs and views of the public, is more likely to produce results that can be used to improve practice in health and social care. INVOLVE uses the term members of the public (or public) to cover:

- patients and potential patients
- people who use health and social care services
- informal (unpaid) carers
- parents/guardians
- disabled people
- members of the public who are potential recipients of health promotion programmes, public health programmes, and social service interventions
- groups asking for research because they believe they have been exposed to potentially harmful substances or products (e.g. pesticides or asbestos)
- organisations that represent people who use services.

Involvement in research refers to **active** involvement between people who use services, carers and researchers, rather than the use of people as participants in research (or as research 'subjects'). Many people describe involvement as doing research *with* or *by* people who use services rather than *to*, *about* or *for* them.

### Ways members of the public can be involved in research

#### Consultation

Consultation involves asking members of the public for their views about research, and then using those views to inform decision-making. This consultation can be about any aspect of the research process - from

identifying topics for research, through to thinking about the implications of the research findings. Having a better understanding of people's views should lead to better decisions.

### **Collaboration**

Collaboration involves active, on-going partnership with members of the public in the research process. For example, members of the public might take part in an advisory group for a research project, or collaborate with researchers to design, undertake and/or disseminate the results of a research project

### **User controlled research/user led research**

User controlled research is research that is actively controlled, directed and managed by service users and their service user organisations. Service users decide on the issues and questions to be looked at, as well as the way the research is designed, planned and written up. The service users will run the research advisory or steering group and may also decide to carry out the research. Some service users make no distinction between the term user controlled and user led research, others feel that user led research has a different vaguer meaning. They see user led research as research which is meant to be led and shaped by service users but is not necessarily controlled by them. Control in user led research in this case will rest with some other group of non-service users who also have an interest in the research, such as the commissioners of the research, the researchers or people who provide services.

INVOLVE produces a range of publications which are free and can be downloaded from the website [www.invo.org.uk](http://www.invo.org.uk) or contact INVOLVE if you would like a copy sent to you. INVOLVE also have a research database which has examples of involving the public in research [www.invo.org.uk/Database.asp](http://www.invo.org.uk/Database.asp).

### **For further information from INVOLVE on active public involvement in the research process see:**

- Turner M and Beresford P (2005) User Controlled Research - its meanings and potential, INVOLVE.
- Public involvement in research grant applications: guidelines for researchers. INVOLVE.
- Hanley B et al (2004) Involving the public in NHS, public health and social care research: Briefing notes for researchers. (second edition) INVOLVE.

### **Contact:**

INVOLVE

Support Unit

Upper Market Street

Eastleigh

Hampshire SO50 9FD

Tel: 023 80 651088 Textphone: 02380 626239 Email: [admin@invo.org.uk](mailto:admin@invo.org.uk) Website [www.invo.org.uk](http://www.invo.org.uk)

## **2) People in Research ([www.peopleinresearch.org](http://www.peopleinresearch.org))**

People in Research is a [UK Clinical Research Collaboration](#) project that has been led by one of its partner organisations, [INVOLVE](#) (see section 1). The [UK Clinical Research Collaboration](#) is a partnership of academic, charitable, commercial and government organisations working together towards a shared vision of the UK as a world leader in clinical research. The ultimate aim is to benefit patients and the public by increasing the health and wealth of the UK. UKCRN and others believe that including the perspectives and experiences of patients and the public is an essential part of shaping the future environment and culture of clinical research in the UK.

**Contact:** [Tel: 020 7670 5153](tel:02076705153) or [Email: peopleinresearch@ukcrc.org](mailto:peopleinresearch@ukcrc.org)

## **3) NIHR Patient & Public Awareness ([www.nihr.ac.uk/awareness.aspx](http://www.nihr.ac.uk/awareness.aspx))**

NIHR promotes the involvement of patients and members of the public in research that meets their needs, is more reliable and more likely to be put into practice. This includes in:

- Setting research priorities
- Helping to decide what the research is setting out to achieve
- Choosing the methods used to carry out the research
- Recruiting people into research studies
- Understanding what research findings mean for patients and how it can be applied in the health service
- Publicising the results.

NIHR has put structures in place that will help people take part in all the stages of NHS research. The NIHR Central Commissioning Facility is committed to active involvement in all stages of research by:

- People who use health and social care services
- Informal carers and families
- Members of the public who may be targeted by public health programmes
- Organisations representing the users of NHS services and community groups.

*The NIHR-CCF contact for Patient and Public Involvement (PPI) is Jean Cooper Moran, Senior Programme Manager, NIHR-CCF, PO Box 407, Teddington TW11 0XX.*

*Tel: 020 8943 7648. E-mail: [jean.coopermoran@nihr-ccf.org.uk](mailto:jean.coopermoran@nihr-ccf.org.uk) (Not to be contacted for general i4i enquiries).*

**FOR GENERAL ENQUIRIES ABOUT THE i4i PROGRAMME PLEASE USE THE FOLLOWING CONTACT METHODS:**

[i4i.programme@nihr-ccf.org.uk](mailto:i4i.programme@nihr-ccf.org.uk) or Tel: 01494 432277

**NOTE: Please ensure that you place “FPD3a” in the subject box of any email sent to the NIHR CCF.**