

## HEALTH INNOVATION CHALLENGE FUND

### Guidance Information For Applicants Submitting Preliminary Applications

#### THEME 5

### Infection Response Systems: Development and application of technology for prevention, diagnosis, intervention and control of infection

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**CLOSING DATE: September 2<sup>nd</sup> 2011**

## 1 Introduction

### HIC Fund Summary

The Health Innovation Challenge Fund (HIC Fund) is a scheme of up to five years supported in equal measure by the Department of Health and the Wellcome Trust.

Its objective is to:

1. Stimulate the development and uptake of innovative products, technologies and interventions for the benefit of patients in the NHS and beyond
2. Target unmet needs in healthcare and seek specific solutions from UK organisations via a succession of themed calls for proposals
3. Provide 'gap-funding' for projects that have reached 'proof-of-concept' and have the potential for clinical use or adoption within 5 years
4. Encourage the collaboration and integration of companies, academia and clinicians to better confront today's healthcare challenges

### Positioning of HIC Fund & Project Criteria

The scheme is positioned as a translational funding mechanism for projects at a later stage in the development pathway than is traditional for basic science projects. Eligible projects will have:

1. A validated 'proof-of-concept'
2. The potential to deliver a product/healthcare solution within 5 years
3. An outline business plan that takes into account the regulatory pathway, IP management, commercial barriers, health economics and the practicalities of introducing the project output to health professionals, patients and the NHS.

The 'innovation' can arise from a number of areas including, but not limited to: Medical devices, Diagnostics, Pharmacogenetics on existing medicines, Tools for preventative medicine, Therapeutics, Regenerative medicine, Healthcare informatics and Healthcare treatments. The 5-year timeframe is likely to preclude de novo discovery for drug development, vaccines and some branches of regenerative medicine.

Funding is intended to take the product, technology or intervention to a stage where it is sufficiently developed to be attractive to:

1. Commercial organisations for follow-on development and taking the product to market, e.g. VCs, corporates
2. Not-for-profit organisations that can offer expertise & resources to assist with the evaluation and development of products, e.g. National Institute of Health Research
3. National healthcare providers if the product is ready for procurement and adoption e.g. NHS

The HIC Fund launches two themes per year with up to £10m available per theme. There is no set limit on the funds that can be awarded to an R&D project although there is a strong emphasis on 'delivery' with tranche payments only being released when milestones are achieved.

Project exclusion criteria are:

- Proposals that are likely in their own right, to be able to obtain sufficient funding from industry/venture capitalists to deliver on their objectives (since the purpose of HIC Fund is to support projects to the point at which they can attract additional funding from commercial sources to complete the pathway to market)
- Development of healthcare products , which are already commercially viable (the HIC Fund assists the development of a technology from a point at which the basic concept is ready to test)
- Pure health services within the NHS
- Health delivery research by the NHS where the focus is on the broad adoption, dissemination and uptake of products, technologies and interventions within the NHS
- Litigation e.g. with respect to patents, or other matters
- Sales & marketing

**Note:**

The Wellcome Trust is a global charity dedicated to achieving extraordinary improvements in human and animal health.

The Department of Health is a Government Department which, aims to improve the health and wellbeing of people in England.

## 2 Funding Limits & Duration

Awards will normally be for a period of up to 3 years.

There is no set amount for the size of these awards. This will be determined on the basis of the justified costs of developing innovative concepts and intellectual property that is either attractive to follow-on developers/investors or is ready for deployment.

**Preliminary Application Forms** should indicate a reasonably accurate estimate of the total funds required. Short-listed applicants will be required to provide a more detailed cost breakdown in the **Full Application Form** together with a final funding request figure. It is accepted that the final figure may differ slightly from the initial estimate.

DH and WT both support research activities but their funding mechanisms differ. Consequently the final funding provided to a successful HIC Fund applicant reflects a combination of these approaches. The notes below summarise the key points for applicants:

- The HIC Fund will provide project funding, not core support or working capital
- **Higher Education Institutions (HEIs)** should calculate the **Full Economic Cost (FEC)** of their bids and submit a request figure for the full 100% FEC
- DH will fund its share of the project costs at up to 100% of FEC. WT will fund the directly incurred costs and other allowable costs.
- Research funding requests should not include **NHS Treatments Costs** or **NHS Support Costs**. In the Full Application Form these costs will need to be quantified although they are not eligible for funding via the HIC Fund. For projects involving patients please refer to the guidance concerning NHS Treatment and Support costs at [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4125280](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125280)
- NHS organisations may include costs relating to management, patent searching, market assessments and economic viability of the ultimate product
- All funding will be paid in tranches on delivery of agreed **milestones**

## 3 Application & Selection Process

### 3.1 Preliminary application process

1. Applicants should download and complete the **Preliminary Application Form**, which is available from the HIC Fund websites mirrored at <http://www.hicfund.org.uk> and <http://www.wellcome.ac.uk/hicf>.
2. Applicants should email completed application forms to [applications@hicfund.org.uk](mailto:applications@hicfund.org.uk) before 5pm on the closing date. The Joint Secretariat will acknowledge receipt within 2 days. If you do not receive an acknowledgment please contact the team – details can be found at <http://www.hicfund.org.uk/ContactUs.aspx>

### 3.2 Project Assessment and Award Process

Assessment of preliminary applications will be made by an expert committee the (**Joint Funding Panel (JFP)**) that includes representatives of the Wellcome Trust and the Department of Health but is independent of both and whose role is advisory only. Preliminary applications will be reduced to a shortlist and successful applicants will be invited to submit a full application. Details on the full application process will be provided to them at that time. The HIC Fund Secretariat will notify all applicants of the JFP's decision within 7 days of the shortlisting meeting.

All invited full applications will undergo external peer review. During this review process the Wellcome Trust and the Department of Health will exchange information contained in the application and peer review feedback. Applicants have the opportunity to respond in writing to reviewers comments.

All applicants are required to present their proposal in person to the JFP by attending a funding committee meeting held at the London office of the Wellcome Trust. The HIC Fund Secretariat will notify all applicants of the JFP's decision within 7 days of the funding meeting.

Successful applicants will be expected to enter into a Funding Agreement that will govern matters such as:

- Scope of project and usage of funds
- Project management, oversight and reporting requirements
- Development milestones
- Confidentiality
- Intellectual property
- Dissemination of results
- Revenue and equity sharing

A specimen Funding Agreement may be viewed and downloaded from the HIC Fund websites.

### 3.3 Project Assessment Criteria

All proposals for funding under the HIC Fund programme will be assessed against the following criteria:

#### 1. The evidence of clinical need and healthcare relevance of the proposed technology/solution

- What is the clinical need for the proposed technology/solution within the NHS and globally?
- How will the proposed technology address healthcare priorities within the NHS and beyond?
- What benefits does the proposed technology provide to both the NHS and patients, e.g. healthcare improvements and/or cost savings?

- How will clinical practice be affected by using the technology and will this lead to constraints in adoption?

## **2. The strength of the project team**

- Does the project team have a strong track record in relevant areas?
- Does the project team have the right skills and experience to deliver the identifiable benefits?

## **3. The strength of the project plan**

- Are the aims and objectives realistic within the timeframe and within the resources proposed?
- Does the project plan adequately address the aims and objectives?
- Have the main technical and regulatory barriers and key risks to successful completion of the project been identified and will the appropriate steps be taken to mitigate these?
- Are the arrangements for managing the project adequate?
- Are the arrangements for involving patient/user representatives appropriate?

## **4. The innovative nature of the technology/solution**

- What is innovative about the proposed technology/solution and what advance is there over current science and technology?
- Will any new intellectual property arise from this project?
- What are the competitor clinical practices and technologies and how strong is the market competition?
- Is there freedom to operate in this area?
- What are the market opportunities, both domestic and global, and the expected impact of the proposed technology/solution?
- What are the key stages and challenges on the route to market? Is the commercial strategy for the technology appropriate?

## **5. The value for money provided by the proposal**

- Are the requested resources, including staffing, clearly justified? Are they essential for the work proposed?
- Taking into account the expected benefits of the work proposed and the level of resources requested, do the proposals promise good value for money?

### **Important Notes:**

1. Any invitation to apply for HIC Fund funding from the WT and DH does not necessarily mean that such funds will be forthcoming
2. Projects must fit within the overall scope and aim of the HIC Fund and comply with the requirements of the:
  - DH Research Governance Framework (<http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/index.htm>)
  - WT policies and position statements (<http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/index.htm>)
3. Applicants must provide clear development and post-funding commercialisation plans and are obligated to follow these plans as part of the Funding Agreement. To ensure that non-commercialised and/or unsuccessfully commercialised IP is utilised to achieve maximum healthcare benefits HIC Fund funding contracts will include intellectual property reversion clauses to allow WT and DH to take the lead in exploitation in the event that the funding recipient does not do so within an agreed timeframe.
4. Applicants are expected to provide adequate information for their proposal to be properly assessed. In some instances it will be necessary to disclose proprietary or unpublished information in order for the Joint Funding Panel to arrive at a fully informed decision.
5. Applicants should be aware that all project applications (and any supplementary information provided) are available to selected staff of the WT, DH and to external advisors for the purpose of short-listing. The WT and DH operate a conflicts of interest policy and place obligations of confidentiality on their staff and external advisors (some of whom are employed in the industrial or financial sectors). Whilst the funders attach great importance to their policies and procedures concerning confidentiality and conflicts of interest, they cannot provide any warranty to applicants in this regard.
6. The day-to-day business of the funders involves the receipt and review of many confidential applications and consequently it is only under highly exceptional circumstances that they will enter into a confidentiality or non-disclosure agreement with applicants.
7. Under some circumstances applicants may receive feedback on their project proposal. This feedback is meant to inform and guide applicants but is not meant to be definitive. Applicants should seek their own independent advice on feedback and its validity.

## 4 Programme Management

The WT and DH will take an active role in the ongoing management and monitoring of funded projects, including the measurement of progress against the milestones which trigger the release of funds. Key elements of the programme management are listed below:

1. Tranches of funding will be released to award holders on the achievement of pre-determined and agreed project milestones.
2. Progress reports and site visits may be used to evaluate the attainment of defined objectives and milestones .
3. Applicants who are short-listed for submission of a full proposal may be required to engage with independent advisor(s) during the detailed planning of the project, and beyond if the project is funded.
4. The Lead Applicant/Principal Investigator, or alternate, may be required to organise a **Research Steering Group** to oversee the project. The purpose of the Research Steering Group is to provide a focus for the team and bring together internal and external project functions.
5. Intellectual property and translation strategy may be managed via an **Intellectual Property Management Group** that will meet on an 'as-needed' basis
6. Funded projects may be subject to periodic review by a WT and DH convened Project Advisory Group.
7. The applicants are required to appoint a Project Manager to assist in the management of the project.

## 5 Call Timetable

From 2010 the HIC Fund will make two calls for proposals per year. Funding decisions will be made within approximately 6 months from the closing date for preliminary applications.


The Theme 5 timetable is shown below:

Preliminary Application <u>Closing Date</u>	2nd Sep 2011 (5pm)
Short-listing of proposals	October 2011
Full Application <u>Closing Date</u>	13th January 2012 (5pm)
Funding decisions	April 2012

## 6 Guidance on Completing the Preliminary Application Form

These guidance notes are for use in conjunction with the Theme 5 HIC Fund Preliminary Application Form. Whilst completing the form please also consider the project assessment criteria, which appear in Section 3.

## 6.1 General

- **Important:** The application form contains 'ActiveX' controls. Depending on your Microsoft Office security settings you may receive a security alert when you attempt to open the document. If ActiveX and macros are not enabled you will not be able to complete the form. To check your settings:
  - a. In Word 2003, starting at the 'Tools' menu go to Options... > Security > Macro Security and ensure that the Medium or Low buttons are highlighted.
  - b. In Word 2007, starting at the 'Microsoft Office Button'  choose Word Options > Trust Center > Trust Center Settings > ActiveX Settings and ensure that the "Disable all controls without notification" option is NOT selected.
- Non-shaded form field (which are in effect Active X controls) can only be completed using computers running Windows. Mac machines are not compatible with Active X controls.
- Shaded form field text boxes will extend automatically as you type. Any word limits must be adhered to.
- All abbreviations must be defined.
- The application must be complete in itself; no additional pages or appendices will be accepted with the exception of a single document containing images and charts referenced in the application.
- In order for your application to be accepted you must submit the minimal required information. This information includes all of the fields in the application form and failure to complete these mandatory fields will result in your application being rejected on the grounds that it is incomplete.
- Applications which do not conform to these requirements and/or are not suitable for reproduction will be returned to the applicant.

## 6.2 Form Sections

### Summary Table (page 1)

Please enter the following summary information:

- **Project Title** - should be both clearly descriptive and concise. It should contain keywords relevant to the project.
- **Total funding requested** - please provide an estimate of the total funding requested. For HEIs, the total funding requested should be the full **100% FEC value**. For NHS organisations, costs relating to management, patent searching, market assessments and economic viability of the ultimate product may be included. NHS Treatment and Support costs should not be included (see Funding Limits & Duration section).
- **Project duration** - please indicate the expected length of the proposed project in months. Awards are typically up to 36 months in duration.
- **Name/Address of Administering Institution** – this can only be a UK organisation
- **Collaborating Organisation** – please provide the names of other organisations involved

### **1. Lead applicant's details**

Please enter the principal or lead applicant's details. The lead applicant is the investigator who will be the main contributor to, and have ownership of the project if the application is successful. This is the individual with whom the HIC Fund will correspond about the application.

### **2. Commercial Lead or Technology Transfer Officer's details**

Technology Transfer Office means the technology transfer office or group with delegated responsibility for the management of commercial matters arising from university-based research. Applicants applying on behalf of a company or other body should provide the details of an appropriate commercial or business development person.

### **3. Key Information**

Provide only the key information requested and limit text according to the instructions.

### **4. Summary of Proposal**

Provide a concise summary in no more than 200 words that clearly sets out the healthcare need driving the proposal, the solution being developed to address this need, the advantages offered relative to established practices or technologies and the potential impact, which the project may have on healthcare and patient wellbeing.

### **5. Background**

Please explain the size and nature of the problem to be addressed. What is the clinical need for the proposed technology/solution within the NHS and globally? How will the proposed technology/solution address healthcare priorities within the NHS and beyond?

Please provide details of any competitor technologies/market competition. Review the current practices and technologies and explain the anticipated benefits of the new proposed technology to patients, device users, healthcare providers, etc.

### **6. Current Status**

Please describe the work that has already been conducted and current stage of development of your technology. Describe any proof of concept studies that have been conducted to support the validity of the proposed approach. Please also outline the technical challenges to be addressed and overcome.

Note that the HIC Fund is seeking to expedite the timely translation of innovative technologies and will not support basic research. Outputs from projects should be no further than 5 years from market introduction and accessibility to the NHS.

### **7. Details of Proposal**

The information provided in your response to sections 9(a) and 9(b) must, in total, not exceed four pages. Figures, graphs etc. will need to be included on a single separate document.

- a. **Plan of Investigation** - The project plan should be separated into distinct packages each of which identifies well-defined project aims, milestones and

deliverables. A project milestone is a key decision point within the project, and can be either scientific or commercial. Please also refer to Section 7 (Programme Management) of this Guidance Information.

- b. **Project Management** - Identify the project management processes that will ensure that milestones are achieved in a timely manner. Indicate how the project will be managed to deliver the milestones and key objectives, describing in-house expertise and any to be accessed externally e.g. via collaborations. What aspects, if any, are to be outsourced and how will this be managed?

## 8. Potential Healthcare Benefits

Please describe here the project deliverables and explain the benefits, which the proposed technology/solution will provide to both the NHS and patients. How will clinical practice be affected by using the technology/solution? What is the perceived route to adoption and what constraints can be foreseen?

## 9. Expertise & Experience of Team

Please indicate why the project team is well qualified to undertake this research. A brief explanation of the relevant expertise that key members possess should be provided. Explain why the team has the right skills and experience to deliver the identifiable benefits. Where applicable please cite previous examples of the team's ability to develop and deliver innovative healthcare technologies.

## 10. Intellectual Property

- a. **Innovative aspects** - The purpose of the HIC Fund is to stimulate the creation of innovative healthcare products, technologies and interventions. Please explain in this section the novel and innovative features of your proposal. Outline any likely new intellectual property and/or patent applications that may arise from this project and set out the main areas of likely claims.
- b. **Existing patents or applications** - Please provide details of all patent applications filed before the date of your preliminary application, which relate directly to the project outlined. State the funding sources that contributed to the development of the patented technology e.g. company collaboration, research council and/or charity funding and indicate the owner (assignee) of the patent. Where possible give application / publication number(s) and priority date(s) and summarise the inventive step and key claims.
- c. **Freedom to operate** - Indicate whether any freedom to operate searches have been conducted and, if so, their outcome. Otherwise, state whether you are aware of any potential freedom to operate issues in the area of the proposed technology and consider how these issues will be addressed during project management.
- d. **New intellectual property** – Describe the intellectual property that will potentially be created during the project together with the mechanisms established to identify and capture this IP and manage its protection.
- e. **Competing technologies** – Please identify any patented competing technologies that you are aware of.

## 11. Commercialisation

- a. **Competitive advantage** - Describe the competitive advantage of this technology over the other solutions that exist or may be in development elsewhere including advantages in relation to existing NHS practice. Include an assessment of the advantages and disadvantages of other competitive technologies of which you are aware. Describe the competitive advantage of the project team over other researchers in the field.
- b. **NHS Adoption** – Describe the practical steps that will maximise the chances of procurement and early adoption of the proposed solution by the NHS, patients and healthcare professionals
- c. **Commercial strategy** - Explain why, at the end of HIC Fund funding, the technology will be attractive for follow-on investment or commercial exit. What are the strategy and plans for attainment of a commercial exit, and how will they be implemented? What is the rationale behind this route? Are there any clinical, manufacturing, regulatory or marketing issues known that may affect the ability to deliver the product to market?

## 12. Suggested Peer Reviewers

Please suggest three potential peer reviewers who have the relevant expertise to assess your proposal, should it be selected to proceed to the full application stage. These reviewers should be independent and have no conflict of interest with respect to your application.

Your suggestions will be used as only one source of peer reviewers of any full application. We may decide not to approach any of these people to undertake a review.

## 7 Submission Process & Closing Date

Completed application forms should be sent by email to [applications@hicfund.org.uk](mailto:applications@hicfund.org.uk), no later than **5:00pm on Friday September 2nd, 2011**.

Applications submitted after this deadline will be rejected.

**Prior to submitting a Preliminary Application Form applicants should review the HIC Fund Grant Conditions document, which is available at [www.wellcome.ac.uk/HICF](http://www.wellcome.ac.uk/HICF) and [www.hicfund.org.uk](http://www.hicfund.org.uk).**

## 8 Contact Details & Further Information

We wish to ensure that potential applicants fully understand what is needed in their applications before they submit them. We are therefore very happy to respond to requests for clarification of the guidance, although we cannot, of course, provide advice on the content of an application.

Any enquiries should be sent by email to [hicfundenquiries@hicfund.org.uk](mailto:hicfundenquiries@hicfund.org.uk). The joint secretariat for HIC Fund can also be contacted as follows:

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