Application for a BHF Translational Award – Full Application

Please note that this a sample form provided for information only – the full application form must be completed and submitted through Flexi-Grant®.

Principle Investigator & Place of Research

Principle Investigator: *Your contact details have been completed as you have entered these previously. The contact details of participants (e.g. co-applicants, Head of Department, TTO) will automatically be recorded once you have invited them to partake in your application. Please note the system defaults the contact type for participants as a 'collaborator'. The lead applicant can change the contact type for each participant using the edit button in the table below.*

Institution(s): *Please ensure the host institution that will be responsible for approving submission of your application, and administration of any award, is the 'lead organisation' in the table below. You must add at least 1 organisation(s) with a name specified.*

- **You will be asked to provide the Institution Name(s)**

Is this where the research will take place? *(Yes/No)*

- *(If No)* **You will be asked to provide full details for the Institution you propose to carry out the research in.**

Co-applicants

On this page, you should enter details of the contributions of any Co-applicants on your grant application.

Co-applicants are those individuals with responsibility for the day to day management and delivery of the project. Co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery. Skip this page if you have no co-applicants.

Are co-applicants involved? *(Yes/No)*

- *(If Yes)* **You will be asked to provide details for each collaborator and their contribution** *(1000 words max)*

In the text box provide a description for each co-applicant's contribution to the project. Structure your responses as follows – full name of the co-applicant, their institution, the percentage time they will be devoting to the project and what their contribution to the project will be. Separate each entry with a blank line.

You can only enter a maximum of 1000 words into this text box. If you have multiple co-applicants, prioritise space for describing the contributions of the main co-applicants. At the same time, be concise when you only have a limited number of co-applicants. If multiple co-applicants are making the same contribution (e.g. recruiting patients for a clinical study), you should enter an individual line for each co-applicant's details, but you can provide a single description of their contribution for all of them.

Collaborators

On this page, you should enter details of the contributions of any Academic Collaborators on your grant application. Please note that you should refer to the Intellectual Property section for the disclosure of any commercial collaborators.

The role of a collaborator is normally to provide specific expertise on particular aspects of the project but who do not share in the responsibility for the delivery of the project.

Skip this page if you have no collaborators.

Are Academic Collaborators involved? *(Yes/No)*

- *(If Yes)* **You will be asked to provide details for each Academic Collaborator and their contribution** *(1000 words max)*

In the text box, provide a description of each collaborator's contribution to the project. Ensure you also attach a letter of support for each named collaborator using the upload box at the bottom of this page.

Structure your responses as follows – full name of the collaborator, their institution, the percentage time they will be devoting to the project and what their contribution to the project will be. Separate each entry with a blank line. You can only enter a maximum of 1000 words into this text box. If you have multiple collaborators, prioritise space for describing the contributions of the main collaborators. At the same time, be concise when you only have a limited number of collaborators. If multiple collaborators are making the same contribution (e.g. recruiting patients for a clinical study), you should enter an individual line for each collaborator's details, but you can provide a single description of their contribution for all of them.

Attach letters of support for each named academic collaborator using the upload box at the bottom of the page.

Project Details

Title of proposed research: This should be no more than 50 words and reflect the aim of the proposed research. You can include special characters in the title.

Please only use a capital letter on the first word of your title and not for any other characters. An example would be: *Medical research project*

Scientific Abstract: *(200 words max)*

Research Activity: Please select the relevant UKCRC Research Activity Code. Only one can be selected.

Subject Code: Select up to five BHF Subject Codes

Keywords: You may enter multiple keywords; please separate them using a comma. E.g. Peripheral arterial disease, Paediatric cardiology *(30 words max)*

Lay Summary: our lay summary may be published on our website and used to help us communicate BHF research to our supporters and the general public. Please write concisely and in simple terms e.g. suitable for a 12-year-old child. Refer to our online guidance for samples of how to write your Lay Summary *(200 words max)*

Proposed Start Date of Grant: Please factor in how long it may take from submission to decision into the proposed start date. Select date.

Suggested Reviewers: Please enter any suggested reviewers below.

Conflicted Reviewers: Please enter any conflicted reviewers below.

Duration of Each Milestone: For each milestone please enter milestone number, duration in months, milestone start point (month) and milestone end point (month) into the table.

Do the Milestones Overlap? *(Yes/No)*

- *(If Yes)* **Please provide justification as to why** *(200 words max)*

Is this a continuation of a grant? *(Yes/No)*

- *(If Yes)* **Continuation of award number**
- *(If Yes)* **End date of previous grant**
- *(If Yes)* **Summary of aims and achievements of previous grant and a list of resulting publications** *(500 words max)*

Is this a resubmission? *(Yes/No)*

- *(If Yes)* **Resubmission of (Case Reference).** Please refer to your outcome email to find the relevant case reference.
- *(If Yes)* **Resubmission of Grant Type**
- *(If Yes)* **Explain how the application has changed from the original submission** *(400 words max)*

Explain how this application does not overlap with any existing work scientifically or financially. This should include any research you are carrying out supported by the BHF or other funders *(200 words max)*

Are there other funding bodies and / or BHF committees that have considered / are considering any part of this application (financially or scientifically)?

- *(If Yes)* **Name of body/committee**
- *(If Yes)* **Result (or date of expected result)**

Project Plan

Background: Please describe the following

a) **Clinical unmet need and target population:** Describe the clinical unmet need that you are seeking to address and define the target population *(200 words max)*
b) **Describe your proposed technology** *(200 words max)*
c) **How will your technology change clinical practice?** *(200 words max)*

d) **Details of validation studies conducted to date and the supporting date that validates your technology** *(500 words max)*
e) **Evidence that your target is relevant to the human disease** *(200 words max)*

Current market and competing solutions: Please describe the following

a) **Describe current market landscape:** *(200 words max)*
b) **Competing solutions:** Describe the competing solutions and their stages of development *(200 words max)*
c) **Competitive advantages of your proposed technology:** Briefly outline the advantages of your solution in comparison to the current technologies and any known technologies under development *(200 words max)*

Long-term plans: Please describe the following

a) **Plans for future development activities:** What are the subsequent development steps that would need to take place before the technology could be taken to the market? Are there any clinical, manufacturing or regulatory issues known that may affect the ability to deliver the product to market? *(200 words max)*
b) **Description of the impact (academic, economic, societal) the proposed Translational Award will have if successful:** Describe the potential impact of your technology being developed to enhance the quality of life and improve public health. How will it benefit the wider research community? Public engagement activities may be included as one element of your pathway to impact, please describe any planned activities *(200 words max)*

Intellectual Property

It is expected that this section should be completed in partnership with your Institution's Technology Transfer Office (TTO) or equivalent.

The definition of Intellectual Property (IP) includes patents, know-how, trademarks, designs, copyright (such as new software, protocols, questionnaires, toolkits, guidelines or similar) and research tools (such as data analysis techniques, assays, cell lines, biomarkers, materials, devices).

What relevant background IP (patents, know-how, design, right, copyright etc.) is held by the applicants and how does it relate to this application? IP may include: Patents (provide patent number), Know-how, Trademarks, Designs, Copyright (e.g. software, checklists, protocols, questionnaires etc.), Research tools (e.g. techniques, devices, assays, cell lines, biomarkers etc.). If access to background IP that is owned by another party (academic and/or commercial) who is not involved with the project (third party IP) is required for the project, you will need to obtain permission to use this IP. Has this permission been obtained? *(300 words max).*

Has a freedom to operate search been conducted and by whom? *(Yes/No)*

- *(If Yes)* **Please provide details of the search and if you require any access to background IP (e.g. licenses etc.)** Consider whether there are any freedom to operate issues in the area of the proposed technology and consider how these will be addressed. All related IP not owned by any of the applicants should be listed, including details relating to third party

licence requirements. If access to background IP held by any third party (commercial and/or academic) is required, has access been agreed? *(150 words max)*
- If no, please explain why not? *(150 words max)*

Are there any commercial collaborators involved? *(Yes/No)*

- *(If Yes)* **Name of Company**
- *(If Yes)* **Type of Collaboration:** Explain the nature and scope of the commercial collaborator's contribution to the project and what they expect in return. Where relevant, explain their long-term strategy in relation to the technology you are proposing to develop *(500 words max)*
- *(If Yes)* **Please attach a copy of the agreement**

Do any of the academic applicants have a direct or indirect interest (consultancy, shareholding, options etc.) in the commercial collaborators? *(Yes/No)*

- *(If Yes)* **Please describe what is the nature of their interest and how conflicts of interest are being managed** *(150 words max)*

Will any IP be produced or improved during the proposed research? *(Yes/No)*

- *(If Yes)* **What IP will be produced or improved during the proposed research? Outline any likely commercially exploitable IP that may arise from this project.** Please describe what new IP will be produced and explain how the proposed project will add value to or strengthen an existing IP position. If commercially exploitable IP is anticipated, please describe the proposed route to market and commercialisation *(200 words max)*

Is the proposed research likely to lead to any IP which may be commercially exploited (e.g. via a patent, know-how, copyright etc.)? *(Yes/No)*

- *(If Yes)* **Please give brief details of the potential IP**

Who will own the foreground (arising) IP? Please explain and include any IP agreements between collaboration partners (commercial and/or academic) if applicable *(100 words max)*

IP Management: Please describe how any new IP generated through the proposed research would be recognised, protected, managed and utilised either via dissemination, implementation into healthcare system or through commercial exploitation (if applicable). Please give details on who will lead on dissemination and/or exploitation *(300 words max)*

IP Exploitation and Commercialisation: Please describe your plans and strategies regarding further development and IP exploitation and commercialisation. Please give details of the anticipated route to the market and commercialisation. Describe the anticipated route to the market and commercialisation, including regulatory considerations and any potential commercial barriers *(250 words max)*

How will the Translational Award de-risk your technology and what are the immediate next steps it will allow you to take? *(100 words max)*

Human Details

Will humans or human tissue be used? If your research will not involve any humans or human samples, select No and move to the next page. If your research will involve humans or human samples, you will be asked to provide details on power calculations in your Case for Support document. *(Yes/No)*

- ***(If Yes, the following 3 questions will be asked)***

Are you recruiting and/or following up living patients/people? *(Yes/No)*

- ***(If Yes, the questions from Total number of patients/subjects onwards will be asked)***

Does your proposal involve tissue/blood samples only?
Answer **Yes** to this question if you are performing research on human samples only, and you are not conducting a clinical study that involves performing tests on people (other than taking samples), phenotyping of people or follow up. *(Yes/No)*

Status of ethical committee approval.
If required, ethical approval does not need to be in place at the time of submitting your grant application, but a copy of ethical approval must be provided to the BHF before an awarded grant can commence. If ethical approval is not required, select that option in the drop-down list and explain why not. *(Approved/Pending/To Be Submitted/Not Required)*

- *(If Approved)* **Date Approved?**
- *(If Approved)* **Please upload a copy of your ethical approval**
- *(If Pending)* **Expected date of result**
- *(If To Be Submitted)* **Date to be submitted?**
- *(If Not Required)* **Please explain why ethical approval is not required**

Total Number of Patients/Subjects.

Refer to MHRA guidance when answering the next two questions.

Does your study involve a Clinical Trial of an Investigational Medicinal Product (CTIMP)? *(Yes/No)*

Does your study require MHRA approval? *(Yes/No)*

Which organisation is the sponsor for the study?

Will a Clinical Research Network (CRN) (or equivalent in the devolved nations) be involved? *(Yes/No)*

- *(If Yes)* **Give the name of the lead CRN**
- *(If No)* **Please explain why one is not involved**

Name, address and email address of NHS Trust R&D manager or equivalent who will be responsible for confirming NHS R&D approval.

(Budget table) **Insert itemised details of the estimated NHS Support, Treatment and/or Excess Treatment Costs associated with the study.** Refer to Costing a Clinical Study and Excess Treatment

Costs before filling in this table. All costs must conform with the AcoRD guidelines.

(Budget table) **AcoRD Part B Research Costs. Please specify proposed research costs that fall under Appendix A, Part B of the AcoRD guidelines.** These include: local study coordination and management, data collection, completing the clinical report form, regulatory preparation, time taken by Chief Investigator and Principal Investigator to explain the protocol.

If you have not included NHS Support Costs or AcoRD Part B Research Costs, explain who will be covering these costs.

Have you discussed the anticipated NHS Support Costs with the appropriate CRN contact (or equivalent in the devolved nations)?

- *(If Yes)* **Please provide details** *(100 words max)*
- *(If No)* **Please explain why not** *(100 words max)*

Name, address and email address of lead CRN contact (or equivalent in the devolved nations) responsible for the proposed NHS Service Support.

Name, address and email address of lead NHS Trust contact responsible for the proposed Treatment or Excess Treatment Costs.

Have you involved a Clinical Trials Unit (CTU)? *(Yes/No)*
Refer to the BHF's guidance on Clinical Trials Units.

- *(If Yes)* **Name, address and email address of CTU member involved with the study**
- *(If Yes)* **CTU Name and Registration Number**
- *(If No)* **Please explain why not**

Name and location of the site(s) where research will be undertaken.

Animal Details

Will animals or animal tissues/other samples be used? *(Yes/No)*
You must select **Yes** to this question if your research will involve the use of any live animals or animal tissue/other samples. If you are only using samples that have previously been collected, you must identify the species used, number of samples and the number that were genetically modified. You are not required to answer the other questions, which relate to use of live animals.

(If Yes, the following questions will be asked)

Does your proposal involve the use of animals covered by the UK Animals (Scientific Procedures) Act 1986? *(Yes/No)*

(If Yes) **Has the Home Office granted the necessary approvals?** *(Yes/No)*

- *(If Yes)* **Project licence number. You can enter more than 1 licence however each**
- **licence number may be no longer than 50 characters.**
- *(If Yes)* **Project licence holder. You can enter more than 1 licence holder.**

- *(If Yes)* **Project licence date of issue. Enter more than one date of issue if you have**
- **included multiple licenses.**
- *(If No)* **Please justify the lack of current Home Office approval.**

Does your proposal involve the use of animals outside the UK? *(Yes/No)*

- *(If Yes)* **Your application will be subject to further review by NC3Rs.** Please provide further details and justification of the location chosen for the animal work. Animal research conducted outside the UK must, as a minimum standard, be carried out in accordance with the principles of UK law and regulation. Refer to the NC3Rs guidance for contracting animal work.

What is the maximum severity of the procedures outlined in the proposal?
(Mild/Moderate/Severe)

- *(If Moderate)* **Please provide details of moderate procedures.**
- *(If Severe)* **Please provide details of severe procedures.**

Please select the animal species to be used *(Cats/Chickens/Dogs/Frogs/Guinea Pigs/Mice/Pigs/ Rabbits/Rats/Sheep/Zebrafish/non-human Primate/Other)*

(For each species of animal used, you will have to provide the number of animals used, indicate whether they are genetically modified and answer species specific questions detailed below)

Number of animals used.

Genetically Modified. Check here if there is genetic modification *(checkbox)*

If using Chicken, frog, guinea pig, mouse, rabbit, rat, zebrafish, other animal.
Please justify your use of animals including the appropriateness of the species and model chosen. Also briefly outline the experimental design, with any plans to reduce bias such as blinding or randomisation. A justification of the proposed sample size must be given along with details of the planned statistical analyses. Power calculations must be included in this section if appropriate. Please refer to the NC3Rs ARRIVE guidelines and Responsibility in the use of animals in bioscience research for further guidance *(1000 words max)*

Have all those involved in the care and use of animals received formal training? *(Yes/No)*

If using Cats and Dogs
Please justify your use of animals including the appropriateness of the species and model chosen. Also briefly outline the experimental design, with any plans to reduce bias such as blinding or randomisation. A justification of the proposed sample size must be given along with details of the planned statistical analyses. Power calculations must be included in this section if appropriate. Please refer to the NC3Rs ARRIVE guidelines and Responsibility in the use of animals in bioscience research for further guidance. Your application will be subject to further review by NC3Rs *(1000 words max)*

From where will the animals be sourced? *(50 words max)*

Will it be necessary to transport the animals? If so, indicate approximate journey times and the measure that will be taken to minimise the potential stress during transport. Describe the conditions for the animals at the breeding establishment and how potential stress during transport will be

minimised. *(200 words max)*

Please provide details of the housing for the animals, e.g. enclosure size, environmental enrichment, socialisation and exercise (socialisation and exercise are particular concerns with dog husbandry) *(200 words max)*

Will single housing of the animals be necessary at any time? If so, please provide details in terms of the justification for single housing, its duration and what additional resources will be provided to the animals to minimise the impact of the single housing *(200 words max)*

Describe the experimental procedures involved and how any pain, suffering, distress and/or lasting harm will be minimised. When were the procedures last reviewed by the NVS, NACWO and AWERB? *(200 words max)*

Will any of the experimental procedures involve food and/or water control? If so, justify why this is necessary and outline what alternatives have been considered *(200 words max)*

Will any of the experimental procedures involve restraint? What alternatives have been considered? Describe the nature of the restraint, its duration and frequency, and what will be done in these areas *(200 words max)*

What prior experience and training in animal use, care and welfare do staff members named in the application have? What provision is made for continuing professional development in these areas *(200 words max)*

Will any of the staff involved require specific training for any of the procedures concerned? Please provide details of the training needed and where it will be undertaken *(200 words max)*

Do you envisage any advances arising from the research that might lead to replacement, refinement or reduction of the use of animals? If so, what might they be, and how do you propose to disseminate such findings? *(200 words max)*

If using Non-human primates
Please justify your use of animals including the appropriateness of the species and model chosen. Also briefly outline the experimental design, with any plans to reduce bias such as blinding or randomisation. A justification of the proposed sample size must be given along with details of the planned statistical analyses. Power calculations must be included in this section if appropriate. Please refer to the NC3Rs ARRIVE guidelines and Responsibility in the use of animals in bioscience research for further guidance. Your application will be subject to further review by NC3Rs *(1000 words max*

Funding/Support Requested

On this page, you must provide details for the budgets for your proposed research project, using the table below. **Before you begin, ensure that you have read our grant costing guide.**

The table has been pre-populated with three rows under each budget heading. You can remove unused rows by clicking the **Remove Item** button next to the item and add extra items using the **Add a New Item** button at the bottom of the table. The **Edit Item** button can be used to change the name of the item. You should change the name to reflect what it is (e.g. change '*Post 1*' to the name of the

person being employed, or write '*Un-named*' if applicable).

Salary costs

Insert salaries for staff employed on fixed term contracts to work specifically on the funded project. BHF has changed how salaries should be costed. Information on this is provided in the grant costing guide. Please confirm the percentage of inflation you have included in your salary costs in the Percentage of inflation included in salary costs box.

Outsourcing costs

We provide funds if you need to outsource project work to parties who are undertaking work on a contracted/out-sourced basis (e.g. contract research organisations (CROs)). They will carry out a specific piece of work on behalf of the investigators on a fee-for-service basis, with no potential claim as an inventor over any arising IP.

Costs for outsourcing should be included in the relevant milestone.

Consumable costs

Provide a full breakdown of all materials required to complete the research, referring again to the grant costing guide for eligible/ineligible costs. If carrying out clinical research imaging scans (e.g. MRI, PET, Echo) refer to our guidance for costing these scans.

Animal costs

You are advised to complete this section in consultation with your animal house or biological services manager, having also used the appropriate tools to accurately cost your animal research.

Equipment

Items of equipment may be included in an application if permitted and specifically required for the project. You will need to attach a quote for each item costing £5,000 or more using the upload box provided.

Travel fund

Access to a travel fund to present research at or attend scientific meetings relevant to the grant will be available if requested and included in the application, with a maximum of £1,000 per year allowed to be requested.

You will be asked to complete a budget table with costs under the following headings:

- Salary
- Consumables
- Animal research costs
- Equipment
- Travel Fund

Additional sources of support for project other than BHF?

Justification for salary support requested: *(1000 words max)*

Percentage of inflation included in salary costs?

Brief CV (two A4 sides including email address) of named staff for whom salary is requested *(upload button)*

Justification for outsourcing requested: *(1000 words max)*

Justification for consumable support requested: *(1000 words max)*

Justification for animal research support requested: *(1000 words max)*

Justification for equipment support requested: *(1000 words max)* And upload any quotes obtained for requested equipment

Quotes obtained for requested equipment *(upload button)*

AMRC Form *(upload button)*

As an Association of Medical Research Charities (AMRC) member, BHF monitors the full economic costs (FECs) of the research we support. You must download a copy of the AMRC costing form provided, complete it and upload a completed form using the upload box below. Acceptance of a grant, if awarded, will imply that the institution is prepared to meet the full economic costs from its own sources of funding.

Additional Information

Please attach a single PDF containing the information requested below in the order instructed.

1) Title of proposed research.
2) Specific objectives/milestones and expected deliverables including justification of experimentation.

   Structure the project in non-over lapping progression milestones, the last one being the project end. For each milestone, please set out the success criteria that will be used to ascertain whether the milestone has been met successfully. Each milestone can have several objectives. Milestones should focus on major progress point that must be reached in order to achieve long term project goals. Milestones should have the estimated timeline, details of key experiments or work to be done and clearly defined GO/NO GO decision points with SMART success criteria (i.e. specific, quantifiable, measurable, achievable, relevant, realistic, time-framed). For the final milestone, the criteria should reflect outcomes representing successful of the project.

3) Timelines in Gantt chart format/similar graphical overview of tasks to be undertaken and their sequence and duration for the entire project. Please mark which tasks the BHF funding will be contributing to and any other funds that are contributing to related project tasks.
4) If applicable provide justification that your chosen outsourcing/CRO options are the most appropriate, providing evidence that others were considered.
5) Graphs, figures, tables and essential unpublished data to support the application (**max four A4 sides**)
6) List of references relevant to the proposed project.

Sections 1-4 must not exceed four A4 sides. Please ensure Arial font size 12 is used. If this font size is not used, the application will be rejected prior to formal consideration.

Principle Investigator Declaration

You will be asked to complete the following declaration:

I have completed an application for a grant in accordance with BHF guidelines. I have read and will comply with the BHF Standard Conditions of Grant and consent to the information I have provided in this application being used accordingly. I also agree to advise the BHF of any change to my status within the host institution, or that of my co-applicant(s), or any scientific, managerial or administrative issue, that might affect the direction of the research. (checkbox)

Head of Department

Head of Department – you must read and agree to the stated declaration by checking the box at the bottom of the page and clicking the Save Progress button.

- I confirm that I have read and support this application, and that I am not aware of any relevant information that has been withheld.
- I agree to the research being carried out in my department and will provide the necessary accommodation and facilities.
- I confirm that the salaries of the principal investigator and co-applicants (unless applied for here) are guaranteed during the term of the grant.
- I also confirm that I have read and accept the BHF Standard Conditions of Grant and that all necessary licences and approvals will be obtained before the project commences.
- I understand that I (or my successor) would be required to vouch for the research that has been completed by signing the Final Report at the end of the grant period.

Technology Transfer Office

Technology Transfer Office - you must read and agree to the stated declaration by checking the box at the bottom of the page and clicking the Save Progress button.

- I enclose an application for a grant completed in accordance with BHF guidelines.
- I have read and will comply with the BHF Translational Grant Terms & Conditions and consent to the information I have provided in this application being used accordingly.
- I also agree to advise the BHF of any change to my status within the host institution, or any scientific, managerial or administrative issue, which might affect the direction of the research.