Application summary

Application title

Proposed duration of funding (months)

Proposed start date	

Name of administering organisation

Lead applicant's address at administering organisation	
Department/Division	
Organisation	
Street	
City/Town	
Postcode/Zipcode	
Country	

Scientific area Please select from the drop-down list the Expert Review Group that you consider your research falls under

Lead applicant

Lead applicant details	
Full Name	
Department	
Division	
Organisation	
Address Line 1	

City/Town	
Postcode	
Country	
Telephone No.	
Email Address	

ORCID ID	
ORCID iD	

Career history (current/most recent first)				
From	**To**	**Position**	**Organisation**	

Education/training				
From	**To**	**Qualification**	**Subject**	**Organisation**

Source(s) of personal salary support for the proposed duration of award

Clinical status Do you have a medical/veterinary degree?	

Please specify

Are you clinically active?	

What is your specialty?

Please specify

Career breaks Have you had any career breaks or periods of part-time work, for example parental or long-term sick leave?	

Please provide details

Do you wish to undertake this award part time?	

Career contributions What are your most important research-related contributions to date? These may include contributions to health policy or practice, or to technology or product discovery and development. (350 words max.)

Peer-reviewed publications and other research outputs List up to ten of your most significant publications, including original research publications and other scholarly contributions, and other research outputs, e.g. patents. You may provide a summary of your contribution to, or your role in, the work associated with each (e.g. intellectually conceiving or conducting the research, supervising staff, writing the paper.) For original research publications indicate those arising from Trust-funded grants in **bold**, and provide the PMCID reference for each of these. Please refer to guidance notes. *Publications should be in chronological order with the most recent first. Please give citation in full, including title of paper and all authors*.* *(*All authors, unless more than 10, in which case please use 'et al', ensuring that your position as author remains clear.)*

Total number of peer-reviewed publications which you have authored/co-authored. Please exclude abstracts and literature reviews.	

Are you a named author on any Wellcome Trust funded original peer-reviewed research papers, published from October 2009 onwards?	

Are all your Wellcome Trust funded original peer-reviewed research papers, published from October 2009 onwards, compliant with our open access policy?	

Current and recent research funding (including Wellcome Trust grants) Please list all held in the last five years and any key prior grants (list the most recent first). State the

name of the awarding body, name(s) of grantholder(s), title of project, amounts awarded, your role in the project, and start and end dates of support. For all active grants, indicate the number of hours per week that are spent on each project.

Organisational support Please provide details of any support (space, facilities, equipment, infrastructure, technical or other assistance) that will be available to you at your organisation (200 words max.)

Collaborators

Will you require any key collaborators for this proposal?	

Please list any key collaborators* (name and organisation) and provide a very brief outline of their role in the proposed research. **The collaborators named may be replaced with suitable alternatives should it be necessary or appropriate to do so.*

I confirm that the collaborators named above have agreed to be involved, as described, in the proposed research and are willing for their details to be included as part of this application.

Related applications

Is this or a similar application for funding currently under consideration elsewhere?	

Please provide name(s) of funding organisation(s) and decision date(s)

Is this a resubmission of an application submitted to the Trust within the last 24 months?	

Project summary

Please provide a summary of your proposal, including key goals. (200 words max.)

Details of proposal

Please detail the following information: (a) aims of the project; (b) the work to be carried out; (c) the expected outcomes; and (d) how this will lead to a larger study (1,400 words maximum).

(1400 words max.)

Does your proposal involve a clinical trial?	

Clinical trial details

What are the proposed participating centres, and the roles of the clinical trial team members? Provide details of any activity to be undertaken by a third party, and comment on the plans to ensure the presence of a formal contract. (200 words max.)

Please describe the study design, including planned interventions (experimental and control), duration of treatment, and any potential significant risks to participants. Details of any investigational product should be provided with particular regard to manufacture, quality and consistency.
(300 words max.)

Describe the inclusion/exclusion criteria. What are the proposed methods for protecting against sources of bias? What are the proposed arrangements for allocating participants to trial groups?
(200 words max.)

What are the envisaged primary and secondary outcome measures, and how will these be assessed at follow up? Describe the proposed frequency and duration of follow up and any anticipated problems with non-compliance and/or loss to follow up.
(200 words max.)

Detail and justify the sample size and proposed statistical analysis, including any interim analyses and/or subgroup analyses. Outline and justify the strategy for recruitment.
(200 words max.)

How have patients, patient advocacy groups or communities been involved in developing the

clinical aspects of this proposal? (300 words max.)

Describe anticipated regulatory and governance approvals, and the proposed arrangements for trial management. What is the proposed membership of the Trial Steering Committee and the Data Monitoring and Ethics Committees? (200 words max.)

You may submit additional information of up to three figures in support of the proposal.

References You should give the citation in full, including title of paper and all authors.

Are there any papers listed in your 'References' section as being "in press" that you wish to submit to us?	

Upload papers "in press"

Location of activity

Will the funded activity take place at more than one location?	

For each location, select the country and, where applicable, state the organisation (please include the administering organisation).	
Country	**Organisation**

Will the funds awarded be allocated to more than one location?	

For each location, please select the country, state the organisation and enter the value and currency of funds to be allocated. Please include the administering organisation.			
Country	**Organisation**	**Value of funds**	**Currency**
			-

Costs requested and justification

Please select the currency in which you wish to apply.

Is the selected currency your local currency?	

What is your local currency?	

Please state clearly the reasons for requesting costs in the selected currency (100 words max.)

Synchrotron radiation sources Will the proposed research require access to a synchrotron source?	

Which source(s) will you be applying to? (Please select all that apply)

Please specify:

Are you requesting costs from the Trust?	

Are you requesting research management costs under the miscellaneous costs heading? (for applicants from low- and middle-income countries only)	

Please upload a letter from the Finance Director of the host organisation confirming that your request for research management costs is a true representation of the costs incurred.

Justification for resources requested Please provide a brief justification for the resources requested. (300 words max.)

Full economic costing

Is your organisation based in the UK?	

Is your organisation calculating the full economic cost of this proposal?	

What is the total full economic cost (£)?	

Research involving human participants, human biological material and identifiable data

Does your project involve human participants, human biological material, or identifiable/potentially identifiable data?	

Please confirm that you have read the Trust's guidance on the feedback of health-related findings in research and that you are in the process of considering your approach to this.

Please state by whom and when the ethics of the project has been, or will be, reviewed and specify any other regulatory approvals that have been obtained, or will be sought. We reserve the right to see relevant approval documents at any point during the lifetime of the grant, in accordance with our policy position on research involving human participants.

Is the proposed clinical trial covered by The Medicines for Human Use (Clinical Trials) Regulations in the UK?	

Please confirm that the trial will be registered on the International Standard Randomised Controlled Trial Number Register (ISRCTN), ClinicalTrials.gov, or on another register listed on the WHO International Clinical Trials Registry Platform (ICTRP).

In the course of your project, do you propose to use facilities within the National	

Health Service (NHS) or to involve patients being cared for by the NHS?	

Is a formal sponsor required for the project, for example under the Medicines for Human Use (Clinical Trials) Regulations or the Research Governance Framework for Health and Social Care and equivalent guidance?	

Please indicate which organisation(s) has/have agreed to fulfil this role. Please note that the Wellcome Trust cannot act as sponsor.

If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, please confirm that there has been appropriate informed consent for such use.

Proposals involving animals

Please indicate which of the following apply: *(Proposal involves the use of animals, Proposal involves the use of animal tissue, Neither of the above)*

Do your proposals include procedures to be carried out on animals in the UK which require a Home Office licence? If yes, refer to notes.	

Do your proposals involve the use of animals or animal tissue outside the UK? If yes, refer to notes.	

If your proposals do involve the use of animals, what would be the severity of the procedures?

Please provide details of any procedures of substantial or moderate severity (250 words max.)

Why is animal use necessary: are there any other possible approaches? (250 words max.)

Indicate which of the following species will be used *(Primate, Cat, Dog, Equidae, Genetically Altered Animals, Other animals)*

Why is the species to be used the most appropriate? (250 words max.)

Justification for animals (number and species) to be used Please include evidence or calculations for experimental group sizes, and describe any plans to reduce bias (e.g. blinding, randomisation). (500 words max.)

Primates

Do you expect facilities and practices, and the proposed research will comply with the principles set out in the 'National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) Guidelines: Primate accommodation, care and use' ?	

Please explain why not

Will it be necessary to transport the non-human primates (i.e. from breeding facility and within the host organisation environment)?	

Indicate approximate journey times and the measures that will be taken to minimise the potential stress during transport.

Please provide details of the housing for the animals, e.g. enclosure size, environmental enrichment.

Will single housing of the non-human primates be necessary at any time?	

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 on animal welfare.

Describe the experimental procedures involved and how any pain, suffering, distress and/or lasting harm will be minimised. Have the procedures been recently reviewed by the Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officer (NACWO) and ethical review process (ERP)?

Will any of the experimental procedures involve food and/or water restriction?	

Justify why this is necessary and outline what alternatives have been considered.

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 to avoid distress.

What prior experience and training in non-human primate use, care and welfare have the staff named in the application had? What provision is made for continuing professional development in these areas?

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.

Cats and Dogs

From where will the animals be sourced?

Will it be necessary to transport the animals?	

Indicate approximate journey times and the measures that will be taken to minimise the potential stress during transport.

Are animals to be imported?	

Where animals are to be imported, what journey times have been agreed with the Home Office? Describe the conditions for the animals at the breeding establishment and how the potential stress during transport will be minimised.

Please provide details of the housing for the animals, e.g. enclosure size, environmental enrichment.

Will single housing of the animals be necessary at any time?	

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.

Describe the experimental procedures involved and how any pain, suffering, distress and/or lasting harm will be minimised. Have the procedures been recently reviewed by the Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officer (NACWO) and ethical review process (ERP)?

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 to avoid distress.

What prior experience and training in animal use, care and welfare will be required of the staff named in the application? What provision is made for continuing professional development in these areas?

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.

Risks of research misuse

Please confirm that you have considered whether your proposed research could generate outcomes that could be misused for harmful purposes.

Have you identified any tangible risks of this type?	

Please briefly describe these risks and the steps that you and your organisation will take to manage them (250 words max.)

Freedom to operate/conflicts of interest

Describe any freedom to operate issues or potential conflicts of interest that have been identified or that might arise and how these will be or have been addressed. In particular, please consider the following: • Do any of the individuals involved in the project hold any consultancies or equities in, or directorships of, companies or other organisations that might have an interest in the results of the proposed research? • Will the proposed research use technology, materials or other inventions that are subject to any patents or other form of intellectual property protection? • Will any element of the research be subject to agreements with commercial, academic or other organisations, including arrangements with collaborators named in the grant application, that might lead to intellectual property issues or restrictions? (350 words max.)

Wellcome Trust supported facilities

Will the project be based in one of the following Wellcome Trust supported facilities: • the Wellcome Trust Sanger Institute • a Wellcome Trust Centre • a Major Overseas Programme • the Francis Crick Institute?	

Please specify