#### Page: Proposal

#### **Section: Application summary**

**Application title** 

**Proposed duration of funding (months)** 

#### **Proposed start date**

You can change your start date if your application is successful. All grant expenditure and activities must be within the grant start and end dates.

#### Research subject area

Select the most relevant area, based on the key aims of the research. This information is used to report on our funding.

#### **Proposal summary**

#### **Proposal summary**

Provide a summary of your proposed research, including key goals, for an expert audience. We will use this as a short abstract and to classify your proposal by subject. We may use it to describe your research on our website and elsewhere (we publish summary details of all our awards). If your application is successful, this summary will be automatically uploaded, without editing, to our website. Take care not to include anything confidential or commercially sensitive.

	maximum	

The summary should be as complete as possible within the word limit. Include key words that best describe the research to enable text searching.

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

We'll consider your application even if you have a similar application being considered by another funder. If the other funder offers you funding, you must tell us immediately. We will usually ask you to decide on that offer within one month. If you decide to apply to another funder with a similar application after you have applied to us, let us know.

Provide the names of any funders and the expected decision dates. (200 words maximum)

#### Research vision

Describe your research vision. Ensure that you provide any further additional information requested on the call's webpage or by your Wellcome contact. In your description make sure you include:

- your aims and research questions;
- the expected outcomes from your work;
- · the background and work which has led up to the project;
- · your approach, methods and how you will address challenges; and
- key stages in your research plans, indicating location and milestones.

If more than one organisation will be involved in the project, indicate what work will be undertaken at each organisation.

Do not exceed 3,000 words.

Provide all relevant information within the application form; do not refer to additional unpublished information on personal websites.

You may provide your answer to this question in text entry format or as a PDF attachment. If you are uploading your proposal, the uploaded document must be in 11 point Arial font and portrait format.

If essential to the proposal, you should embed figures, graphs, tables in the text. You can upload other additional essential information separately, for example: references, unpublished data, letters of support. The additional information should not be an extension of the proposal.

(3,000 words maximum)

#### Additional information

Ensure that you provide any further additional information requested on the call's webpage or by your Wellcome contact.

#### References

Include any references needed to justify your proposal. You should give the citation in full, including title of paper and all authors. 'In press' publications may be included only if they are available on preprint servers.

(1,500 words maximum)

You may provide up to the equivalent of two A4 pages of references. Ensure that your references are pertinent to your research proposal and are cited in full, including all authors, the full title of each publication, journal title, year, volume and pages.

You can shorten references with more than 10 authors to 'et al', but you must ensure that your position as author (if applicable) remains clear.

Describe the steps needed beyond this funding to achieve the impact from this proposal. (500 words max.)

These may include, for example:

- steps needed to produce a product that can be maintained over time such that it can be used directly by those with mental health problems
- steps needed to ensure policy makers adopt practices based on the findings
- steps needed to ensure service providers change practice based on the findings
- steps needed to ensure findings from basic science are used to help target or develop interventions.

#### Lived experience

Explain how you have involved, and will involve, people with lived experience of anxiety, depression and/or psychosis as relevant in multiple stages of the design, delivery, and dissemination of the project. As part of this explain:

- Your approaches to involving people with lived experience at each stage of the project in detail, including development of this proposal.
- How you plan to identify and recruit people with lived experience with the relevant skills to
  work on the project. State the relevant skills and expertise you are looking for from the people
  with lived experience with whom you plan to work.
- How the proposed research meets priorities of people with lived experience.
   (500 words max.)

People with lived experience should be appropriately compensated or paid for their time. Include information on this under the "Costs requested and justification" section, along with any additional costs needed to ensure your lived experience involvement plans are appropriately budgeted for. See the guidance on involving people with lived experience on our website for further information on how to involve people with lived experience in your research (LINK to https://cms.wellcome.org/sites/default/files/2023-

07/Wellcome%20Lived%20Experience%20information%20July%202023%20-%20FINAL.pdf).

Are you collecting new data from human participants on depression, anxiety or psychosis?

Do you agree to use one or more of the required measures in line with the guidance described on our website?

You are welcome to also collect any other measures you choose.

Why do you not intend to use one or more of our required measures? (100 words max.)

Does your proposal involve human participants or human biological material?

(Yes - only involves human participants, Yes - only involves the use of human biological material, or identifiable or potentially identifiable data, Yes - involves both human participants and the use of human biological material, or identifiable or potentially identifiable data, No - does not involve human participants or human biological material)

We use the World Health Organization definition of research with human beings: "any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings:

- are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment or
- become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records."

Read our Research involving human participants policy for information on what we expect from the researchers and organisations we fund.

#### Details of study design for research involving human participants

Describe the study design. This should include, as applicable:

- number of participants, respondents or ethnographic subjects in each group
- how you will allocate participants to study groups
- type, frequency and duration of interventions, health outcome measures, interviews, focus groups or participant observation sessions
- any locations of research involving human participants
- details and justification for the power calculation, sample size and proposed statistical analysis – explain the methods for protecting against bias
- form, frequency and duration of planned follow-up
- long-term follow up or respondent care plans
- any other activity with potential significant risks to participants.

(700 words maximum)

Types of health outcomes or interventions can include but are not limited to:

- screening procedures
- collection of biological samples
- biometric and clinical data
- experimental challenges
- behavioural treatments.

Outline your strategy for recruitment and describe the inclusion or exclusion criteria for study participants (if applicable). If your research includes a clinical trial you must also tell us:

- how you will comply with our policy on ensuring the inclusion of under-served groups and
- how your recruitment and retention methods will engage with under-served groups (300 words maximum)

How have you involved patients, participants, patient advocacy groups or communities in developing this proposal? What ongoing involvement will they have in the research? (200 words maximum)

Describe the oversight arrangements for the study. For example, the membership and composition of the Steering Committee and Data Monitoring Board. (300 words maximum)

Who has, or will, review the ethics of the project and when? Detail any other regulatory approvals you have, or will try to get.

We reserve the right to see relevant approval documents at any point during the grant and after it has ended. This is in accordance with our research involving human participants policy. (200 words maximum)

Before research begins, you must have in place:

- ethical approval in every country where any part of the research will be carried out
- the relevant regulatory and ethical approvals for every site where research will be carried out
- appropriate governance mechanisms.

Read our guidance on research involving people living in low- and middle-income countries.

You must have ethical approval for any research Wellcome funds that involves:

- human participants
- human biological samples
- personal data.

Any use of personal data or biological samples, relating to living or dead persons, must comply with all relevant legislation where you are working.

You must get approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority (HFEA) or the Gene Therapy Advisory Committee in the UK where necessary. For example, research involving human embryos may need a licence from the HFEA. See the <u>HFEA website</u> for more information.

If your proposal involves research on gene therapy which needs regulatory approval, you should apply for this from:

- your Local Research Ethics Committee
- your University's Genetic Manipulation Committee
- the Gene Therapy Advisory Committee
- the Medicines and Healthcare products Regulatory Agency (MHRA).

Researchers based outside the UK must tell us what the law and guidelines are in the area or jurisdiction in which they will be collecting samples, and how they will comply with these.

Will you be using facilities, staff or patients within the National Health Service (NHS) in the UK?

By agreeing to fund work which needs NHS support, Wellcome agrees to abide by the Statement of Partnership on Non-

commercial R&D in the NHS in England (and the corresponding statements in Northern Ireland, Scotland, and Wales). You must therefore meet the obligations of the Partnership and may not carry out any research until the NHS has given its consent.

The Research Governance Framework for Health & Social Care, published by the Department of Health in England can be downloaded from the Department of Health website. Wellcome cannot act as sponsor.

Have you completed a Schedule of Events Cost Attribution Tool (SoECAT)? This must be signed off by an AcoRD specialist. Download a template SoECAT from the National Institute for Health and Care Research (NIHR) website. Read our guidance on why you need to complete a SoECAT.

Upload the study information page and the summary page of your signed off SoECAT form as a single PDF.

[IF NO] Explain why you could not complete a Schedule of Cost Attribution Tool. You can submit your SoECAT while we are reviewing your application but Wellcome cannot make a funding decision without it. If you do not have a signed-off SoECAT form your research will not receive Health Research Authority approval (or equivalent). (100 words maximum)

Which organisations have agreed to act as the formal sponsors for your project? (100 words)

All research involving human participants, tissue or data (including clinical trials) must have a sponsor. For example, under the Research Governance Framework for Health and Social Care or the Medicines for Human Use (Clinical Trials) Regulations 2004.

If your trial is based in the UK, then you must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004. In accordance with this regulation, applicants must identify a sponsor who fully understands the responsibilities and costs associated with assuming this role. This is usually a university or NHS Trust. Wellcome cannot act as sponsor.

Researchers based outside the UK must tell us what the law and guidelines are in the area or jurisdiction in which they are working, and how they will comply with these.

Confirm you have, or you will try to get, appropriate informed consent to use any potentially commercially exploitable results from tissues or samples derived from human participants. Where data has the potential to be used beyond its initial purpose or beyond the end of the study, include details for how the consent will be managed.

Answer 'not applicable' if no potentially commercially exploitable results (based on human tissues or samples) will be produced during your research, and if no potential future use of data.

Does your proposal involve a clinical trial?

The World Health Organization defines a clinical trial as: "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions

include, but are not restricted to, drugs, cells and other biological products, surgical procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."

For more information read Wellcome's clinical trials policy.

If your proposal involves more than one clinical trial, contact Wellcome for advice.

Confirm that the trial will be registered on one of the following:

- International Standard Randomised Controlled Trial Number Register (ISRCTN)
- ClinicalTrials.gov
- another register listed on the WHO International Clinical Trials Registry Platform (ICTRP).

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

Under the Medicines for Human Use (Clinical Trials) Regulations 2004, applicants must identify a sponsor who fully understands the responsibilities and costs associated with assuming this role. This will usually be a university or NHS Trust. Wellcome cannot act as sponsor.

Describe the oversight arrangements for the clinical trial (e.g. membership of Trial Steering Committee, Data Monitoring Board etc.)

Are you applying with coapplicants?

#### **Team composition and management**

Describe the roles of all applicants and how the project will be managed and led. (500 words maximum)

#### Section: Outputs management and sharing

#### Provide an outputs management plan

All Wellcome-funded researchers are expected to manage their research outputs in a way that will achieve the greatest health benefit, maximising the availability of research data, software and materials with as few restrictions as possible. Read <u>our guidance on developing an outputs management plan</u>, which includes a link to some good examples.

If an outputs management plan is not required, please briefly explain why below. (500 words maximum)

Your plan should be clear, concise, proportionate and focus specifically on how outputs will be identified, managed and

used to advance potential health benefits.

You should use the following questions as a template for your answer.

For Data, software and materials outputs

- 1. What outputs will your research generate?
- 2. What metadata and documentation (for example the methodology of data collection and way of organising data) will accompany the outputs?
- 3. When will these outputs be made available?
- 4. Where will you make these outputs available?
- 5. How will these outputs be discovered and accessed by the research community? (for example through presentations or press releases)
- 6. Are there possible restrictions to data sharing or embargo reasons?
- 7. How will data and metadata be stored, backed up and preserved?
- 8. What resources (for example financial and time) will be dedicated to outputs management and ensuring all data is findable, accessible, interoperable and reproducible?

If your study involves a clinical trial, please see the clinical trial specific guidance on the webpage. This includes additional points you must specify when your outputs include participant data.

For Intellectual property (IP) outputs

- 1. What IP will your research generate?
- 2. How will you protect this IP?
- 3. How will the IP be used to achieve health benefits?

Provide the name and contact details for the person in your organisation (for example Technology Transfer Officer or Business Development executive) who can act as a point of contact for Wellcome to discuss the protection and commercialisation of this IP.

Select the approach you will use to maximise the impact of your significant research outputs to improve health and benefit the wider research community. If an outputs management plan is not needed, select 'Not applicable'.

(Make research outputs available for access and re-use, Protect intellectual property and/or commercialise outputs, A combination of both approaches, Not applicable)

#### Section: Collaborations

Are any collaborations essential for this proposal?	
	1

A collaborator provides essential subject related expertise, support or materials. They are not involved in the day-to-day running of the research. They are not normally involved in the intellectual design of the project.

They are not remunerated for their input, although expenses can be covered, for example for their grant-related travel and the costs associated with providing the agreed input into the research, including the materials and consumables involved.

List any key collaborators (name and organisation) and provide a very brief outline of their role in the proposed research.					
Name Organisation Outline of role in proposed research (50 words maximum)					

You can replace the collaborators named here with suitable alternatives if it is necessary or appropriate to do so.

I confirm that the collaborators named here 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.

#### **Section: Location of activity**

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

List any locations outside of your host organisation where you will be conducting research or redirecting funds. This includes, but is not limited to, anywhere receiving indirect funding, Wellcome Trust supported facilities, fieldwork sites, and time spent working in another organisation or laboratory. This does not include conference attendance.

## For each location, select the organisation and then select 'Edit' to add the country and percentage of funds. You must include the administering organisation.

Enter the approximate percentage of the total funds that will be spent in each location. Enter zero for locations where activity will take place but no significant funds will be spent. If you are requesting salary costs, attribute them to the employing organisation.

## Will the project be based in one of the following Wellcome Trust supported facilities:

- the Wellcome Trust Sanger Institute
- a Wellcome Trust Centre
- an Africa and Asia Programme
- the Francis Crick Institute?

If the project will be based at one of these facilities, you must add the facility as a location.

#### Will you need funds to be awarded directly to more than one location?

We will only consider requests for funds to be awarded directly to more than one location if your grant either:

- includes a request for multiple currencies any request for additional currencies must be at least the equivalent of £750,000
- involves an organisation based in a low- or middle-income country we will assess the financial capacity of the organisation to manage the grant.

If we award directly to more than one location, we will not move funds between organisations after we have issued the award letter.

Explain why you need these funds to be awarded directly to more than one location. (200 words maximum)

For each location, select the country, state the organisation and enter the value and currency of funds. You must include the host organisation.

Country	Organisation	Value of funds	Currency

#### Section: Research involving animals

Does your proposal involve the use of animals or animal tissue?

(Yes - involves animals, Yes - involves animal tissue, Yes - involves animals and animal tissue, No - my proposal does not involve animals or animal tissue)

The following notes relating to 'Proposals involving animals' are intended to provide guidance and advice in completing the form, rather than a comprehensive review of the legal and regulatory environment in which the application is made.

Applicants must refer to our policy on the use of animals in medical and veterinary research.

In all animal experiments we support, the principles of reduction, replacement and refinement will apply. In all experimental studies, applicants must actively consider:

- the complete replacement of live animals with tissues derived from either animals or humans
- the possibilities of reducing the numbers of animals that need to be used
- refining the experimental design to obtain the maximum amount of information from the minimum number of animals.

Refined methods in animal research are those which alleviate or minimise any adverse effects for the animals involved, or enhance animal welfare. Refinements may be applied at any stage in the life of an animal. Thus, refinement encompasses all aspects of a procedure, including the:

- source, transport, husbandry and environment of the animals involved
- experimental design (for example, the choice of species and the group size employed)
- techniques applied
- end points of the procedures
- care of the animals before, during and after a procedure.

For further information about the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), check their website.

#### Monoclonal antibodies

The use of ascitic animals for monoclonal antibodies (mAb) production in vivo may only be proposed when in vitro attempts at mAb production have failed or the use of animals is considered justified for specific diagnostic or therapeutic products. You must give a full explanation if in vitro production methods are not considered to be suitable.

Explain why animal use is necessary and the choice of species to be used. (250 words maximum)

It is particularly important to justify the species when an animal is being used as a model for a human physiological or pathological condition.

Select 'Add...' to enter the animal species and total numbers needed (this may differ from the number to be bought, maintained).

Animal species	Strain (it annronriato)	Total number needed to carry out proposed work
-		

Provide a justification of the proposed sample size and details of planned statistical analyses. Include power calculations if appropriate. Describe experimental design, including any plans to reduce bias such as blinding or randomisation. (750 words maximum)

You may provide your answer to this question in the field provided (text entry format) or as a PDF attachment (upload format). If you are uploading your answer, the uploaded document must be in 11 point Arial font and portrait format.

For each species, you must ensure that adequate experimental detail is provided to justify both the use and number of animals. This should include:

- definition of unit of analysis (for example N referring to animal or sample number)
- means of avoidance of bias (for example blinding or randomisation)
- statistical analysis to be used and explanation of how sample or group size was derived
- the number of time points if repeated measures are used
- an indication of number of replications of each experiment to mitigate spurious non-replicable results.

You may include tables and figures in this section to help justify animal numbers. You can find additional guidance on designing animal experiments through the NC3Rs Experimental Design Assistant.

(750 words maximum)	
Does your proposal include procedures to be carried out on animals in the UK	
which need a Home Office licence? The organisation must ensure that research involving the use of animals	
complies at all times with UK laws and regulations.	
Is there a current Home Office Personal Project Licence (PPL) that authorises the proposed procedures to be carried out in the UK?	
Provide the name of the licence holder.	
Detail your plans and timelines for getting the appropriate licence. (200 words max	ximum)
If your proposal involves the use of animals, what would be the severity of the pro	
You can find guidance on assessing the severity of a procedure on the Home Office	ce website.
Provide details of any moderate, severe or non-recovery procedures. Can lower sibe used?	everity procedures
(250 words maximum)	
Does your proposal involve the use of animals or animal tissue outside the UK?	
Confirm that the proposed animal work outside of the LIK will comply with the prince	ciples of LIK law

Animal research conducted outside the UK must, as a minimum standard, be carried out in

accordance with the principles of UK law and regulation.

Law and regulatory standards often vary from country to country. If experiments are to be carried out on animals outside the UK, the experiments proposed must be performed to standards which follow the principles of UK legislation. Furthermore, the housing and care of animals must similarly follow the standards and principles of UK legislation.

For studies using non-human primates, cats, dogs or equines, this is assessed during NC3Rs review. For studies involving other species, applicants should complete and upload the checklists listed on the NC3Rs website. Read the information on choosing contractors.

If your study does not involve non-human primates, cats, dogs or equines, complete and upload the checklists listed on the NC3Rs website, as appropriate. Upload any checklists as a single PDF. *Read the information on choosing contractors*.

#### Non-human primates

Will you be using primates?	
The NC3Rs will review all applications involving the use of primates, or their tissue or data.	
If you are exclusively using already generated tissue or data in the proposed experelevant questions as thoroughly as possible, in particular the questions relating to procedures. If a question is not relevant you can answer 'not applicable', but we minformation for assessment.	housing and
Do the facilities and practices, and the proposed research comply with the principles set out in the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) guidelines?	
Explain why not (200 words maximum)	
Explain wity not (200 words maximum)	
Will it be necessary to transport the non-human primates (for example from breeding facility and within the host organisation environment)?	
Indicate approximate journey times and the measures that will be taken to minimistress during transport. (200 words maximum)	se the potential
Provide details of the housing for the animals, for example enclosure size, enviror (200 words maximum)	nmental enrichment.
See the NC3Rs guidance on animal housing and husbandry for further details.	_
See the NCSN's guidance on animal nodsing and husbandry for further details.	
Will single housing of the non-human primates be necessary at any time?	
Durantale a traditionation for simple becoming its direction, and complete rule at additional	

Provide a justification for single housing, its duration, and explain what additional resources you will provide to the animals to minimise the impact on animal welfare. (200 words maximum)

Describe the experimental procedures involved and how any pain, suffering, distress 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 Animal Welfare and Ethical Review Body (AWERB)? (200 words maximum)			
Will any of the experimental procedures involve food 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 frequency, and what will be done to avoid distress. (200 words maximum)	duration and		
What prior experience and training in non-human primate use, care and welfare we the staff named in the application? What are you doing to support continuing profedevelopment in these areas? (200 words maximum)			
	T		
Will any of the staff involved need specific training for any of the procedures concerned?			
Provide details of the training needed and where it will be done. (200 words maximum)			
Cats, dogs and equidae			
Will you be using cats, dogs or equidae?			
The NC3Rs will review all applications involving the use of cats, dogs and equidae animals, or their tissue or data.			
Select which species you will be using: (Cats, Dogs, Equidae)			

If you are exclusively using already generated tissue or data in the proposed experiments answer all relevant questions as thoroughly as possible, in particular the questions relating to housing and

information for assessment.	ay ask for more		
From where will the animals be sourced? (200 words maximum)			
	_		
Will it be necessary to transport the animals?			
Indicate approximate journey times and the measures that will be taken to minimis stress during transport. (200 words maximum)	se the potential		
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. (200 words maximum)			
Provide details of the housing for the animals, for example enclosure size, environ	nmental enrichment.		
, , , , ,			
See the NC3Rs guidance on animal housing and husbandry for further details.			
Will single housing of the animals be necessary at any time?			
Provide a justification for single housing, its duration, and explain what additional resources you will provide to the animals to minimise the impact on animal welfare. (200 words maximum)			
Describe the experimental procedures involved and how you will minimise any pain, suffering, distress or lasting harm. Have the procedures been recently reviewed by the Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officer (NACWO) and Animal Welfare and Ethical Review Body (AWERB)? (200 words maximum)			
What adverse effects might the animals experience? List the clinical and other sigmonitored, the frequency of monitoring and, if relevant, the humane endpoint crite the study.			

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. (200 words maximum)

What prior experience and training in animal use, care and welfare will you require of the staff named in the application? What are you doing to support professional development in these areas? (200 words maximum)

Will any of the staff involved need specific training for any of the procedures

Provide details of the training needed and where it will be undertaken. (200 words maximum)

#### Genetically altered animals

concerned?

Will you be using genetically altered animals?

All proposed research projects involving genetically altered mice are expected to consider the principles of welfare assessment set out on the NC3Rs website.

#### Section: Risks of research misuse

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

You and your host organisations must consider carefully any risks that the potential outcomes of the research (information, products or technologies) of the research could be misused for harmful purposes. These are known as "dual use risks" and they include actions that pose a significant threat to humans, animals, plants or the environment, including terrorist misuse.

Research areas that aim to do the following are often associated with this type of risk

- demonstrate how to render a vaccine ineffective
- confer resistance to a therapeutically useful antibiotic or antiviral agent
- enhance the virulence of a pathogen or renders a non-pathogen virulent
- increase the transmissibility or alter the host range of a pathogen
- enable the evasion of diagnostic and detection methods
- enable the weaponisation of a biological agent or toxin
- generate or reconstitute an eradicated or extinct agent or toxin.

Do not include the following types of risk in your answer:

- remote or hypothetical risks of future misuse (we recognise that most research could hypothetically be misused)
- data risks for example breaches of personal data and risks of anonymised recipients being reidentified (should be managed by research design and data management protocols)
- safeguarding risks to researchers and participants (these should be managed by your organisation.

Have you identified any tangible risks of this type?

Refer to the joint BBSRC, MRC and Wellcome policy and position statement on managing risks of research misuse, and our guidelines on good research practice.

Briefly describe these risks. Explain how you and your organisation will manage them. (250 words maximum)

The identification of tangible risks in a research project should be clearly balanced against the benefits and value that is to be gained for health, science and society. If there are tangible risks that the proposed research will generate outcomes that could be misused to cause harm, you (and your fellow researchers and host organisations) must take appropriate steps to monitor the research as it proceeds and minimise these risks. Risk mitigation could include establishing a process to review dual-use risks on an on-going basis through the project and to gain independent expert advice as appropriate. You must also ensure that all members of your team are aware of these risks in progressing their research, and receive appropriate education and training on these issues.

#### Section: Freedom to operate and conflicts of interest

Describe any freedom to operate or other intellectual property related issues that might affect your ability to do the proposed research or to use, share or commercialise the research outputs. Explain how you will address these.

If you are satisfied that there are no such issues, answer 'not applicable'. If you have fully addressed such issues in your outputs management plan under the question on "Outputs management and sharing", then you may refer to that answer.

In particular, consider:

- Will your research use technology, software, databases, materials or patented inventions that are owned or controlled by others and which you do **not** already have written permission to use?
- Will the ownership, use, commercialisation or sharing of research outputs with the wider research community, be subject to agreements with commercial, academic or other organisations? This includes arrangements with collaborators named in this application.

(250 words maximum)

For more information about our approach to intellectual property and translation, refer to:

- Clause 8 of our Grant Conditions
- Our intellectual property and translation page.

Disclose all relevant information pertinent to your grant proposal, including proprietary information where appropriate, to provide the most comprehensive picture of how commercial or IP matters may affect the delivery of your proposed research and the subsequent use, commercialisation or sharing of your research outputs.

Describe any conflicts of interest which might affect your ability to do the proposed research or to share or commercialise the research outputs.

For each conflict:

explain how you and your organisation will manage the conflict

- explain how you will comply with your organisation's conflicts of interest requirements
- confirm whether the identified conflict has been disclosed to your organisation.

If you are satisfied there are no issues, answer 'not applicable'.

Refer to our policy on conflicts of interest related to Wellcome-funded researchers and commercial organisations. In particular, consider whether anyone involved in your project holds any consultancies, advisory roles, or equities in, or directorships of, companies or other organisations that might have an interest in the results of your proposed research.

	maximum	

#### Page: Applicant details

#### Section: Lead applicant details

#### Account profile

Complete, or check and update, the following sections in your Wellcome funding account profile:

- · Basic information about you
- Diversity monitoring information
- C\

#### CV details you must complete in your Wellcome Funding account profile

Education/training					
School	Country	Degree or Qualification	Subject	Start date	End date (or expected)

Career history (current/most recent first)							
Position	Department	Organisation	Country	Start date	End date	Current position?	

#### Career breaks

Have you taken any breaks from research that you would like us to take into consideration? This can include periods of parental or long-term sick leave, caring responsibilities, part-time work, secondments, volunteering or time spent in clinical training or different sectors. You can also include any periods where you were unable to work because of the COVID-19 pandemic.

#### Provide details of career breaks

We take breaks from research into account when we consider your outputs. Tell us when and for

what period you took a break or were working part-time. Don't provide reasons for any career breaks, or share sensitive personal health information. (200 words)

Salary funding sources		
Salary source	Percentage contribution to salary	Type of contract
Are you a healthcare p	ofessional?	
What is your healthcare	e profession?	
Are you clinically active	e?	
What is your specialty?	•	

#### CV details you must complete in the application form

#### Do you want to undertake this award part time?

If you want to undertake this award part-time, either from the start or part way through the grant, your host organisation must employ you on a part-time basis during that time.

We always try to accommodate requests, as long as your employing organisation agrees to the working arrangement. Your Funding Adviser will contact you to acknowledge receipt of your application after the scheme application deadline. You should discuss any flexible working plans with them as early as possible. If you have any questions before you apply, please contact our Research Funding Information Desk.

#### **Current and recent research funding (including Wellcome grants)**

List any funding you have received in the last five years, including current funding, and any key funding in the five years before that.

List the most recent first. Include the name of the funder, name(s) of grantholder(s), title of the project, total amount awarded (and how much of this you received), your role in the project, and the start and end dates. Include the percentage of your time spent on the research.

Include details of any recurrent or core funding you have held. Explain your role in getting the funding. For example, whether you held them in your own right as lead applicant, coapplicant, or as part of a consortium.

We use this to check your eligibility for this award and to understand how this proposal is distinct from other funding you hold.

Describe how the currently active grants listed above relate to this application. If you hold grants related to the topic of this application, explain how these differ and confirm there is no overlap in funding.

(200 words maximum)

This helps us understand how your application is distinct and does not overlap with research activities already supported by other awards.

What percentage of your research time will you spend on this project?

#### Section: Lead applicant research contributions

How have you contributed to the generation of knowledge? Describe how you have contributed to the generation of new ideas, tools or techniques and your most important research outputs so far.

You may highlight skills you have used to develop and test ideas. Please also list up to 10 of your most significant research outputs and describe why they are relevant, what difference they made and your contribution to each (up to 50 words per output). Outputs can include: original publications, open data sets, software, commercial or interventional products or tools, clinical practice developments, educational products, policy publications, and conference publications that you have generated.

If referencing original research publications, please give the citation in full, including the title of paper and all authors (unless more than 10, in which case you may use 'et al', ensuring that your position as author remains clear). Citations to preprints must state "Preprint", the repository name and the articles persistent identifier (e.g. DOI). (1000 words max.)

#### How have you contributed to the development of others?

This may include, for example:

- mentoring and supervision of students and colleagues, or mentoring others in your field;
- examples of strategic leadership, how you shaped the direction of a team, organisation, company or institution; and
- · your involvement in establishing collaborations.

(300 words max.)

#### How have you contributed to the wider research community?

This may include, for example:

- editing, reviewing, refereeing, and your contributions to the evaluation of researchers and research projects;
- organisation of conferences or knowledge sharing activities;
- contributions to improving research culture (research integrity, equality, diversity, mobility of researchers, reward and recognition of researchers' various activities); and
- appointments to positions of responsibility within your department, institution or organisation.

Please do not include any sensitive personal information relating to people you have worked with or supported. (300 words max.)

#### Section: Lead applicant research environment details

Describe how your research contributes to the strategic aims of your organisation. (300 words max.)

Describe your approach to developing and supporting a positive and inclusive research culture, including examples from previous and current groups.

This could include, for example:

- mentoring
- · supporting collaboration and interdisciplinarity
- leadership and people management
- · promoting research integrity.

Please do not include any sensitive personal information relating to people you have worked with or supported.

(500 words max.)

You can find examples of approaches to improving research culture here.

Your organisation will give you and the staff employed on your grant a minimum of 10 days a year to undertake training and continuing professional development. Explain how you will use this time.

(300 words max.)

This may include the responsible conduct of research, research leadership, people management, diversity and inclusion, and the promotion of a healthy research culture.

## Upload a letter from a senior member of your organisation confirming that the organisation will:

- Give the applicant the space and resources they'll need from the start date to the end date of the award.
- Give the applicant and any staff employed on the grant 10 days a year (pro rata if part-time) to undertake training and continuing professional development (CPD) in line with the Concordat to Support the Career Development of Researchers.
- Provide a system of onboarding, embedding and planning for the applicant when they join the organisation and/or start the award.
- Provide the applicant with the status and benefits of other academic staff of similar seniority.
- If teaching buyout is being requested, ensure that the applicant will retain at least 10% of their teaching time and that teaching buyout for the applicant is not being provided by other grants for the same period it is requested on this grant.

If you are based in a low- or middle-income country and you are requesting your salary on this grant, this letter should also confirm:

- that your employment contract states you must get salary recovery from external grant funding; and
- that your host organisation will underwrite the salary and post for the period of time that you will be working on the grant

#### **Section: Coapplicant details**

<u>1</u>	
Coapplicant	
Coapplicant Name	

#### **Account profile**

Complete, or check and update, the following sections in your Wellcome funding account profile:

- · Basic information about you
- Diversity monitoring information
- CV

#### CV details coapplicants must complete in your Wellcome Funding account profile

Education/training						
School	Country	Degree or Qualification	Subject	Start date	End date (or expected)	

Career history (current/most recent first)								
Position	Department	Organisation	Country	Start date	End date	Current position?		

#### Career breaks

Have you taken any breaks from research that you would like us to take into consideration? This can include periods of parental or long-term sick leave, caring responsibilities, part-time work, secondments, volunteering or time spent in clinical training or different sectors. You can also include any periods where you were unable to work because of the COVID-19 pandemic.

#### Provide details of career breaks

We take breaks from research into account when we consider your outputs. Tell us when and for what period you took a break or were working part-time. Don't provide reasons for any career

breaks, or share sensitive persor	nal health information. (200 words)				
Salary funding sources					
Salary source	Percentage contribution to salary	Type of conf	tract		
Are you a healthcare profession	onal?				
NAME AT 1 141 A					
What is your healthcare profes	ssion?				
Are you elimically estive?					
Are you clinically active?					
What is your specialty?					
What is your specialty.					
07. 1.4.11					
CV details coapplicants must o	complete in the application form				
Do you want to do this award	part time?				
	time, either from the start or part w				
the grant, your nost organisation that time.	must employ you on a part-time ba	asis during			
	s, as long as your employing organisation				
Funding Adviser will contact you to acknowledge receipt of your application after the scheme application deadline. You should discuss any flexible working plans with them as early as possible. If you have any questions before you apply, please contact our Research Funding Information Desk.					
What percentage of your research	ch time will you spend on this proje	ct?			

How have you contributed to the generation of knowledge? Describe how you have contributed to the generation of new ideas, tools or techniques and your most important research outputs so far.

You may highlight skills you have used to develop and test ideas. Please also list up to 10 of your most significant research outputs and describe why they are relevant, what difference they made and your contribution to each (up to 50 words per output). Outputs can include: original publications, open data sets, software, commercial or interventional products or tools, clinical practice developments, educational products, policy publications, and conference publications that you have generated.

If referencing original research publications, please give the citation in full, including the title of paper and all authors (unless more than 10, in which case you may use 'et al', ensuring that your position as

author remains clear). Citations to preprints must state "Preprint", the repository name and the articles persistent identifier (e.g. DOI). (1000 words max.)

#### How have you contributed to the development of others?

This may include, for example:

- mentoring and supervision of students and colleagues, or mentoring others in your field;
- examples of strategic leadership, how you shaped the direction of a team, organisation, company or institution; and
- your involvement in establishing collaborations.

(300 words max.)

#### How have you contributed to the wider research community?

This may include, for example:

- editing, reviewing, refereeing, and your contributions to the evaluation of researchers and research projects;
- organisation of conferences or knowledge sharing activities;
- contributions to improving research culture (research integrity, equality, diversity, mobility of researchers, reward and recognition of researchers' various activities); and
- appointments to positions of responsibility within your department, institution or organisation.

Please do not include any sensitive personal information relating to people you have worked with or supported.

(300 words max.)

Describe how your research contributes to the strategic aims of your organisation. (300 words max.)

# Describe your approach to developing and supporting a positive and inclusive research culture, including examples from previous and current groups.

This could include, for example:

- mentoring
- supporting collaboration and interdisciplinarity
- leadership and people management
- promoting research integrity.

Please do not include any sensitive personal information relating to people you have worked with or supported.

(500 words max.)

You can find examples of approaches to improving research culture here.

year to	organisation will give you and the staff employed on your grant a minimum of 10 days a o undertake training and continuing professional development. Explain how you will use me.
	ay include the responsible conduct of research, research leadership, people management, diversity and inclusion, promotion of a healthy research culture.
Unioa	d a letter from a senior member of your organisation confirming that
	ganisation will:
•	Give the applicant the space and resources they'll need for the period of time that they are working on the grant.
•	Give the applicant and any staff employed on the grant 10 days a year (pro rata if part-time) to undertake training and continuing professional development (CPD) in line with the Concordat to Support the Career Development of Researchers.
•	Provide a system of onboarding, embedding and planning for the applicant when they join the organisation and/or start the award.
•	Provide the applicant with the status and benefits of other academic staff of similar seniority. If teaching buyout is being requested, ensure that the applicant will retain at least 10% of their teaching time and that teaching buyout for the applicant is not being provided by other grants for the same period it is requested on this grant.

### Page: Research proposal costs

#### Section: Costs requested and justification

#### Select the currency in which you want to apply.

Submit costs in the currency you think will best enable you to undertake the activity. This will probably be your local currency; if not, explain why not.

If you think that the currency may not be readily available, email grantpayments@wellcome.org. For more information see our website.

We may not be able to award your grant in the currency you have requested. In these situations, we will talk to your administering organisation about using another currency.

Is this your local currency?	
What is your local currency?	

Explain why you are requesting costs in the selected currency and what exchange rate you have used. (100 words maximum)

If you do not have a bank account in the currency you have requested, you will be liable for any increase in research costs due to foreign currency conversions and/or charges.

# Staff Are you asking for staff?

Detail the full employment costs for all staff to be funded on the grant.

If you are based in the UK or Republic of Ireland, you cannot ask for your salary. If you are based in a low- or middle-income country, you can ask for your salary if you hold a permanent, open-ended or long-term rolling contract that states that you have to get your salary from external grant funding.

Provide the names of individuals for posts involving the handling of, and research on, non-human primates. Whilst your application is being considered, you must notify us of any change to the individual(s) named in the application.

#### Definition of terms

**Role:** For example: Postgraduate research assistant, Postdoctoral research assistant, Technician, Fieldworker. Specify the level of seniority of the post where relevant, for example Junior postdoctoral research assistant, Senior postdoctoral research assistant.

Salary grade or scale: The national or local salary grade/scale on which the individual will be employed.

**Basic annual starting salary:** Annual salary to be paid to the individual on their appointment to the post, exclusive of any allowances for which the individual is eligible. If the post is part time, the annual salary must be quoted on a pro rata basis.

**Total cost on grant:** Total cost of the post, inclusive of any locally-recognised allowances (for example, London allowance), employer's contributions and increments, over the period of the grant. Employer's contributions should include any statutory obligations (for example for the UK, National Insurance contributions) and contributions towards an organisational pension scheme.

#### Staff costs

<u>Otani (</u>	50313							
	Number of staff requested for	Role	Name (if known)	Basic annual starting salary	Salary grade or scale	Period on project (months)	% time	Total

#### Justification for staff

Specify the role and responsibilities for the staff requested. Justify the type and seniority, including the level of salary requested, of each post. (300 words maximum)

If any staff requested will be working in different locations, say where they will be working. If you are requesting funds to be awarded directly to more than one location, you must indicate in the cost breakdown where the funds are to be allocated.

Adjustment support	
Are you requesting adjustment support?	

If you or a member of staff employed on your grant is disabled or has a long-term health condition, we offer <u>different types of support during your grant</u>. This includes help to do your project, report on grant progress, and attend events such as researcher meetings.

Enter the cost of the adjustment support you need. We do not need any further information at this stage.

Ad	ljustn	าent S	Supp	ort

Total

#### Training and continuing professional development

Are you requesting training and continuing professional development?

Training and continuing professional development

Cost type	Description	Total

Justification for training and continuing professional development. (200 words maximum)

#### Materials and consumables

Are you requesting materials and consumables?

Provide a high-level breakdown of materials and consumables costs. These typically include:

- laboratory chemicals and materials (for example reagents, isotopes, peptides, enzymes, antibodies, gases, proteins, cell, tissue, bacterial culture, gloves, plasticware and glassware)
- associated charges for shipping, delivery and freight
- archival photocopying
- printing associated with fieldwork

In the justification for materials and consumables, provide an estimate of the cost for each staff member each year.

#### Materials and consumables

Description	Total

Justification for materials and consumables. (300 words maximum)

#### **Animals**

Are you requesting animals?

To ensure animal experimentation costs are accurate, you must complete this section after consultation with your animal house or biological services manager. Your organisation must apply a consistent costing methodology when presenting cost

details.

We may ask for more detailed costing information where a large number of animals and/or substantial costs are involved.

#### **Animals**

Animal species	Total purchase cost	Total maintenance and procedures cost	Total

#### Associated animals costs

Description	Total

These costs cover specific and relevant training and environmental enrichment, including training for animal husbandry, welfare and associated training for animal technicians, and the cost of animal licences.

Justification for animal costs. (300 words maximum)

Do not include a justification of the animal numbers you need; you can explain this in the 'Research involving animals' section.

# Equipment Are you requesting equipment?

The organisation's Director of Procurement/Head of Purchasing (or equivalent) must be aware of all potential capital purchases and we need organisations to use best procurement practice when buying equipment with our funds.

#### Equipment to be bought

We expect you to consider the cost-effectiveness of the proposed purchase of equipment. The estimated price of the equipment must cover all aspects including delivery, installation, maintenance and training, where appropriate. We expect discounts to be negotiated and included in quoted prices.

We normally expect a contribution from the host organisation, or other source, if the application includes a substantial equipment request. If you have any questions about this, contact grantenquiries @wellcome.org.

If there is a preferred manufacturer for certain items of equipment, you can explain this in the 'Type of equipment' field.

We expect that the equipment you request will be covered by the manufacturer's warranty for the first year after it is bought. We will fund reasonable maintenance costs for four years after the initial period of warranty on all equipment (irrespective of the length of grant made), when this is negotiated as part of the capital purchase cost. We will also consider costs for the maintenance of equipment over 5 years old if you can demonstrate that it is cost-effective.

#### Value Added Tax (VAT)

For grants to be held in the UK, the costs of all equipment to be used for medical and veterinary research must be quoted exclusive of VAT. For equipment that does not fall within this definition, VAT costs should be shown.

#### Equipment maintenance

We consider requests for maintenance of existing equipment if the grant that funded its purchase has ended. We only provide maintenance costs for equipment more than five years old if it is cost-effective to keep maintaining it.

#### Equipment costing 100k or more

We need a copy of at least one formal quote for each piece of equipment with a list price of £100,000 or more. The discount that has been negotiated must be included in the quote. We expect a contribution from the host organisation, or other source, if your application includes a substantial equipment request.

**Equipment costs** 

Тур	ре	Type of equipment	Number of items	Cost for each item	_	Contribution from other sources	Total

Justification for equipment. (300 words maximum)

If you are requesting a piece of equipment which costs more than £100,000, provide details of:

- similar equipment in the applicant's department and adjacent departments
- why it cannot be used for this particular project
- any other individuals likely to use the equipment.

Are you requesting a piece of equipment with a list price of £100,000 or more?

Upload a copy of at least one formal quote; if you have more upload these as a single PDF.

#### Access charges

Are you requesting access charges?

You can ask for the cost of access to shared equipment or facilities if they're essential to your research project. These may include materials and consumables, plus a proportion of:

- maintenance and service contracts
- staff time costs for dedicated technical staff employed to operate the equipment or facility.

We don't cover the costs of:

- estates and utilities
- depreciation or insurance
- other staff, for example contributions to departmental technical, administrative and management staff time.

If the facilities or equipment were paid for by a Wellcome grant, you can only ask for access charges if:

- the grant has ended
- any support for running costs and maintenance contracts has ended.

Access charges

Justification for access charges. (300 words maximum)

# Overheads Are you requesting overheads?

Where overheads are allowed and you are including these in your application, provide a letter from the Finance Director of each organisation requesting these costs. The letter must provide a breakdown of the costs requested and confirm that the request is a true representation of the costs incurred.

#### **Overheads**

Description	Total

Justification for overheads. (300 words maximum)

Upload a letter from the Finance Director of each organisation. If there is more than one letter, upload these as a single PDF.

Each letter must include:

- a full breakdown of costs requested (you can't ask for a percentage of the project costs)
- an explanation of why these costs are necessary for the project
- confirmation that the breakdown is a true representation of the costs incurred.

Are you based at a UK university and requesting overheads on subcontracted costs?

Confirm that the university will not include these subcontracted costs in its annual return for the UK Charity Research Support Fund.

# Travel and subsistence Are you requesting travel and subsistence?

Include conference attendance, collaborative visits and other travel related to this grant separately. When necessary, include the host organisation. Enter the total carbon offset costs requested as a single line. Find out more about our carbon offset for travel policy <a href="here">here</a>.

#### Conference attendance

The lead applicant and any research and technical staff to be employed on the grant can request costs to attend academic or scientific conferences, including conference registration fees and carbon offsetting the travel, up to maximums of £2,000 a year for the lead applicant and £1,000 a year for research and technical staff. Specify the amount being requested for each

You can ask for costs that exceed the above limits where academic or scientific conference attendance or dissemination is a core part of the research activity. You will need to strongly justify where such costs are requested.

#### Collaborative visits

If you are requesting costs for collaborative visits, include the host organisation and provide a detailed breakdown of the travel and subsistence costs. Justify the need for each visit, its duration and your mode of transport separately.

	n offset ate your carbon offsetting costs for all the travel on the grant. Tell u	s the number of tonnes yo	u are offsetting a	nd the
Traval	and subsistence costs			
	Description Description		How much carbon will this offset (in tonnes)?	Total
	cation for travel and subsistence. vords maximum)			1
	seas allowances ou requesting overseas allowances?			
Overs Type	eas allowance costs  Description			Total
	cation for overseas allowances. words maximum)			
	work expenses ou requesting fieldwork expenses?			
	vork expenses ription		Total	
			1 0 0 0 1	
	cation for fieldwork expenses. words maximum)			
	cal research			

You can request costs for other essential visits, for example for sample collection and trips to facilities. Justify the need for the visit, its duration and your mode of transport separately.

Other travel related to this grant

Description	Total	
Justification for clinical research. (300 words maximum)		
Public engagement and patient involvement Are you requesting public engagement and patient involvement?		
Public engagement and patient involvement costs		
Description	Total	
Justification for public engagement and patient involvement. (300 words maximum)		
Contract research organisations Are you requesting contract research organisations?		
Contract research organisations		
Description	Total	
Justification for contract research organisations. (300 words maximum)		
Other Are you requesting other costs?		
Provide a detailed breakdown of the other costs requested. Enter costs that do not fall under any of section.	other category in this	
Other costs		
Type Description	Total	
Justification for other. (300 words maximum)		
Summary of costs requested		

	Total
Total	

#### **Section: 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 of your research proposal in sterling (GBP)?	
Include inflation in your costs at the percentage rate currently used by your host organisation.	

#### Page: Information for expert review

#### **Section: Reviewer suggestions**

You can let us know here if there are any reviewers that you suggest are particularly suitable to comment on your application, or those that you consider we should not approach (please provide a brief factual reason).

The information you provide here will not appear in the PDF of the application but will be visible to other participants involved in the application.