

## Application summary

### Application title

*The application title should be clearly descriptive and concise. It should contain keywords relevant to the project. Please note that if this application is successful, this information will be made publicly available and therefore should not contain any proprietary information.*

### Proposed duration of funding (months)

*This should be the total length of time required for the project, including activities such as the writing of final reports.*

### Proposed start date

*Applications should normally be submitted at least three months before the proposed starting date and the project must start within six months of payment of the award.*

### Administering organisation type:

*Please select the relevant administering organisation type (company, university or not-for-profit).*

*Applications are welcome from academic, not-for-profit or commercial organisations based anywhere in the world but may be subject to eligibility checks. Please contact a member of staff if you are unsure whether your organisation is eligible.*

### Name of administering organisation

*Please enter the name of the organisation which will be the recipient of the funds. If your application is successful, this is the organisation that will be responsible for administering the award.*

### Lead applicant's address at administering organisation

Department/Division

Organisation

Street

City/Town

Postcode/Zipcode

Country

*Please enter the lead applicant's address at the administering organisation. If your application is successful, this is the address that will be used in the award letter where appropriate.*

## Lead applicant

| Lead applicant details |  |
|------------------------|--|
| Full Name              |  |
| Department             |  |
| Division               |  |
| Organisation           |  |
| Address Line 1         |  |
| City/Town              |  |
| Postcode               |  |
| Country                |  |
| Telephone No.          |  |
| Email Address          |  |

*The application process requires that there must be one Lead Applicant who will have a significant role in the project, including responsibility for its management and delivery. This individual is responsible for submitting the application form for organisational approval and final submission to the Wellcome Trust and is with whom the Wellcome Trust will correspond about the application.*

| ORCID iD |  |
|----------|--|
| ORCID iD |  |

*Lead applicants must add their ORCID iD. Find out more about ORCID on our website.*

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

*Please provide details of your current position (if applicable) and all previous posts held, listing most recent first.*

| Education/training |    |               |         |              |
|--------------------|----|---------------|---------|--------------|
| From               | To | Qualification | Subject | Organisation |
|                    |    |               |         |              |

*Please provide details of relevant education/training, listing the most recent first.*

| Previous applications  |  |
|--|--|
| Have you ever applied to Innovations at Wellcome for funding before? |  |

*Please select 'Yes' if you have applied for Wellcome Innovations (or previously Technology Transfer) funding before.*

|  |  |
|--|--|
| Have you ever applied for other Wellcome Trust funding before? |  |
|--|--|

*Please select 'Yes' if you have previously applied for Wellcome Trust funding other than via Innovations/Technology*

Transfer.

**Source(s) of personal salary support**

Please state the source of funding of the salary of your post (for example, company salary, or funded through your organisation's block grant from a Higher Education Funding Council). If your salary is being funded from more than one source, please provide details of all funding sources, including their relative contributions. If there are any ties on intellectual property rights or publications arising from the research you undertake, please contact the Wellcome Trust for advice. Restrictions on intellectual property may affect your ability to apply to the Wellcome Trust.

If you are not currently in employment, this question should be answered 'not applicable'.

**Are you requesting your salary as part of this application?**

Current basic salary (per annum)

Currency

Is current salary provided by a Wellcome Trust grant?

Please give the Wellcome Trust grant number

**Clinical status**

Do you have a medical/veterinary degree?

Please note that this includes dental and clinical psychology degrees.

Please specify

Are you clinically active?

What is your specialty?

Please choose your specialty from the dropdown list – if it is not on the list, select 'Other' and specify.

Please specify

**Career breaks**

Have you had any career breaks or periods of part-time work, for example

|                                   |  |
|-----------------------------------|--|
| parental or long-term sick leave? |  |
|-----------------------------------|--|

*We encourage applications from researchers who have taken career breaks, and wish to ensure that any such breaks are duly taken into account when considering your track record. Please state when and for what period of time you took a break, or were working on a part-time basis. We are not seeking any information on the reasons for this break so please do not provide this here, including sharing any sensitive personal health information.*

|                        |
|------------------------|
| Please provide details |
|------------------------|

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| Do you wish to undertake this award part time? |  |
|--|--|

*If you wish to undertake this award part time, you must be employed on a part-time basis. Please contact the Trust to discuss your requirements.*

|                         |
|-------------------------|
| <b>Key achievements</b> |
|-------------------------|

Provide references or examples of five key achievements related to this application, which may include any of the following:

- i) inventions protected by intellectual property rights that have been developed commercially and/or adopted;
- ii) patents that have been issued;
- iii) peer-reviewed publications.

You may also provide a statement describing the significance of each achievement listed (up to 50 words per achievement).

*Achievements must be related to this application. The examples you choose can be taken from any stage of your career. In each case, please state what the achievement was, when it was achieved, why you think it is important, what impact it has had and how it relates to this proposal.*

*We encourage the inclusion of articles published via open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.*

*For original research publications arising from Trust-funded grants, provide the PubMed Central ID (PMCID) reference for each of these.*

*The Wellcome Trust's open access policy requires all original peer-reviewed research papers, supported in whole or in part by Trust funding, to be made available through PubMed Central (PMC) and Europe PMC as soon as possible and in any event within six months of the journal publisher's official date of final publication.*

*The PubMed Central ID (PMCID) is the unique identifier assigned to every full text paper in PubMed Central (PMC) and Europe PMC.*

*Please note that:*

*We actively monitor compliance with our open access policy and successful applicants will be asked to provide a full list of all their Wellcome-funded research papers, and confirm compliance by providing the PMCID identifier for these, before the award letter can be issued.*

*For further guidance, please refer to the Trust's open access policy statement and authors' information*

|  |
|--|
| <b>Current and recent funding plus related activities (including Wellcome funding)</b> |
|--|

Please list all funding received over the last three years including any key grants, partnerships or collaborations (list the most recent first). For grants, please state the name of the awarding body, name(s) of grant holder(s), title of project or enterprise, 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. Please identify with an asterisk(\*) those sources of support that have

contributed to the background of this proposal.

Please list all key forms of financial support in the last three years (commercial, research grant etc.), including Wellcome Trust awards and any recurrent or core funding support. For grants, please state clearly your role in obtaining the funding, for example, whether you held the grant in your own right as lead applicant, co-applicant, or as part of a consortium, partnership or other collaboration. Please state the value of your own component of the award and the percentage of your time spent on the research.

For applicants from companies, please also outline the funding that has been allocated to the development of your healthcare innovation to date, specifying if it was provided by the company and/or external sources.

## Applicants

All applicants are expected to be actively involved in the proposed project. There is no requirement for applicants to be co-located with the lead applicant.

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| Applicant      |  |
|----------------|--|
| Full Name      |  |
| Department     |  |
| Division       |  |
| Organisation   |  |
| Address Line 1 |  |
| City/Town      |  |
| Postcode       |  |
| Country        |  |
| Telephone No.  |  |
| Email Address  |  |

### Career history (current/most recent first)

| From | To | Position | Organisation |
|------|----|----------|--------------|
|------|----|----------|--------------|

### Education/training

| From | To | Qualification | Subject | Organisation |
|------|----|---------------|---------|--------------|
|------|----|---------------|---------|--------------|

All applicants are expected to be actively involved in the proposed project. There is no requirement for applicants to be co-located with the lead applicant.

### Previous applications

Have you ever applied to Innovations at Wellcome for funding before?

Please select 'Yes' if you have applied for Wellcome Innovations (or previously Technology Transfer) funding before.

Have you ever applied for other Wellcome Trust funding before?

Please select 'Yes' if you have previously applied for Wellcome Trust funding other than via Innovations/Technology Transfer.

**Source(s) of personal salary support**

Please state the source of funding of the salary of your post (for example, company salary, or funded through your organisation's block grant from a Higher Education Funding Council). If your salary is being funded from more than one source, please provide details of all funding sources, including their relative contributions. If there are any ties on intellectual property rights or publications arising from the research you undertake, please contact the Wellcome Trust for advice. Restrictions on intellectual property may affect your ability to apply to the Wellcome Trust.

If you are not currently in employment, this question should be answered 'not applicable'.

**Are you requesting your salary as part of this application?****Current basic salary (per annum)****Currency****Is current salary provided by the Wellcome Trust?****Please give the Wellcome Trust grant number****Key achievements**

Provide references or examples of five key achievements related to this application, which may include any of the following:

- i) inventions protected by intellectual property rights that have been developed commercially and/or adopted;
- ii) patents that have been issued;
- iii) peer-reviewed publications.

You may also provide a statement describing the significance of each achievement listed (up to 50 words per achievement).

*Achievements must be related to this application. The examples you choose can be taken from any stage of your career. In each case, please state what the achievement was, when it was achieved, why you think it is important, what impact it has had and how it relates to this proposal.*

*We encourage the inclusion of articles published via open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.*

**Current and recent funding plus related activities (including Wellcome funding)**

Please list all funding received over the last three years including any key grants, partnerships or collaborations (list the most recent first). For grants, please state the name of the awarding body, name(s) of grantholder(s), title of project or enterprise, 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. Please identify with an asterisk(\*) those sources of support that have contributed to the background of this proposal.

Please list all key forms of financial support in the last three years (commercial, research grant etc.), including Wellcome Trust awards and any recurrent or core funding support. For grants, please state clearly your role in obtaining the funding, for example, whether you held the grant in your own right as lead applicant, co-applicant, or as part of a consortium, partnership or other collaboration. Please state the value of your own component of the award and the percentage of your time spent on the research.

For applicants from companies, please also outline the funding that has been allocated to the development of your healthcare innovation to date, specifying if it was provided by the company and/or external sources.

## Technology Transfer Officer

The questions in this section apply to applications from universities only.

Title

Forename(s)

Surname

Employing organisation

Contact address

Email address

Telephone number 1

Telephone number 2

## Collaborators

Will you require any key collaborators for this proposal? These may be located within your current organisation or elsewhere.

These are collaborators who will be making a **significant** contribution towards the proposed research, for example, assisting with specific elements of the research, or providing access to key resources, reagents or samples. If the answer

is 'Yes', you will be asked to provide information of these collaborators and to confirm their willingness to participate in the proposed research.

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.*

*Collaborator involvement should be governed by appropriate legal agreements, such as material transfer agreements, confidentiality agreements and/or consultancy agreements. If such agreements are already in place, copies should be provided with the application.*

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.

Are you providing copies of any agreements with the named collaborators?

Upload agreements

*Please submit agreements as a single PDF.*

## Company information

The questions in this section apply to applications from companies and not-for-profit organisations only.

Is the company publicly listed?

Company number

Date and place of incorporation

Share capital

Authorised

Issued

Registered holders (name, number and type)

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|                   |
|-------------------|
| Registered office |
|                   |

|           |
|-----------|
| Directors |
|           |

|           |
|-----------|
| Secretary |
|           |

|                           |
|---------------------------|
| Accounting reference date |
|                           |

|                                       |
|---------------------------------------|
| Previous source of funding and amount |
|                                       |

|                                    |
|------------------------------------|
| Cash in bank and other investments |
|                                    |

|                             |
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| Average monthly expenditure |
|                             |

|                    |
|--------------------|
| Board of directors |
|                    |

|                           |
|---------------------------|
| Scientific advisory board |
|                           |

|                     |
|---------------------|
| Number of employees |
|                     |

|   |
|---|
| Describe the company's R&D strategy with respect to the <b>proposed project</b> and describe how this proposal would integrate with the current portfolio and strategy.<br>(200 words max.) |
|   |

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| <i>Briefly summarise the overall strategy, competencies and company portfolio as appropriate to the proposed programme. Please do not include any proprietary information.</i> |
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| Please confirm that the company has sufficient working capital and capacity to provide in-kind contributions (if specified) for the duration of the project. |
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## Related applications

|   |  |
|---|--|
| Has this application, or part of this application, been submitted for consideration elsewhere, either previously or currently?  |  |
| <i>The Wellcome Trust will neither consider nor process an application for support where the same or a closely related application is under consideration by another organisation unless agreed in advance with the Wellcome Trust. You are expected to inform us if you decide to submit this or a similar proposal to another funding body whilst the application to the Wellcome Trust is still under consideration.</i> |  |

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

|   |  |
|---|--|
| Is this a resubmission of an application submitted to the Wellcome Trust within the last 24 months? |  |
| <i>Applicants must contact the Wellcome Trust before resubmitting an application.</i>               |  |

|   |
|---|
| Please describe how this application differs from the original (200 words max.) |
|   |

## Project summary

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| <b>Lay summary</b><br>Please provide a summary of your project that people who may not be familiar with the subject can understand. We may edit your summary and then use it to describe your project on our website and elsewhere.  |
| <i>You don't need to oversimplify your research, but try to explain it as clearly as possible. You should write in the first person ("I" and "we") and structure your summary in this order:</i> <ul style="list-style-type: none"><li>• <i>background to the research problem</i></li><li>• <i>your approach</i></li><li>• <i>advantages of your innovation</i></li><li>• <i>expected impact of your work.</i></li></ul> <b>Example of a lay summary</b><br><i>Brain-based disorders, including psychiatric and neurological illnesses, represent 10.4% of global disease. At present, objective tools for detecting and monitoring brain disorders are not available. Deep learning is an area of artificial intelligence which allows detection of complex and distributed patterns in data that are difficult to capture using existing approaches. We will assemble a very large dataset of neuroimaging data from more than 12,000 disease-free people and more than 2,000 patients with psychosis. Using deep learning technology we will develop a model of the disease-free brain across different ages and genders and illustrate how this model can be used to detect neuroanatomical alterations and inform clinical assessment in individual patients. This will lead to the development of a flexible web-based tool for measuring neuroanatomical alterations in any brain-based disorders. This could help clinicians assess the presence of a disease, monitor its progression and optimise treatment in individual patients.</i> |

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| <b>Vision statement</b> |
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What will you achieve with the funding requested and what do you want to achieve in the longer term?  
(200 words max.)

*Provide a concise summary that clearly describes what you aim to do with the funding requested and how this fits into the wider vision for the technology being developed. This should include a summary of what you would hope to achieve in the longer term, beyond the scope of the funding provided.*

### Potential impact summary

Please provide a summary of the potential impact to patients, addressing **all** of the following points:  
(a) What is the global burden of the disease/condition and what proportion of this patient population does your healthcare innovation have the potential to benefit?  
(b) How will your healthcare innovation impact on the health of the target population?  
(c) How are your team uniquely positioned to achieve this?  
(d) Why will funding and support from Wellcome make a difference?  
(500 words max.)

*a) Describe the potential impact of the healthcare innovation being developed, including the global burden of disease, using metrics such as disability-adjusted life years (DALYs) where relevant. Specify what proportion of those affected by the disease or condition could benefit from your solution taking into consideration market accessibility and affordability;  
b) When considering the impact on the health of the target population you should consider whether your solution will need to displace another technology or require a complementary technology in order to achieve impact, for example a companion diagnostic;  
c) State how your team is uniquely positioned to achieve the impact stated (with regard to the complementary skills that they bring and resources that can be accessed);  
d) Specify what the added value of Wellcome funding will be over and above funds that could be obtained elsewhere.*

*Please include your references to support the disease burden statements in the 'Details of project' section of the form and refer to them in this section where appropriate.*

## Project classification

### Classification codes

Please list the relevant specific disease classification codes and regional procedural codes

*For disease-specific classification codes, please refer to the World Health Organisation Classification of Diseases (ICD).*

*e.g. J10.0: Influenza with pneumonia, seasonal influenza virus identified*

*In the absence of an internationally recognised procedural code, please provide a relevant regional code. An example is the OPCS Classification of Interventions and Procedures version 4 or "OPCS-4", which is the procedural classification used by clinical coders within the United Kingdom's National Health Service.*

*If you are unable to provide this information please explain why.*

**Technology Readiness Level** Using the guidance notes, please indicate your technology readiness level:

*Please select from the drop down list the project's starting Technology Readiness Level (TRL) and the level intended to be reached by the end of your Innovator Award. An example TRL metric can be found here:*

[https://ncai.nhlbi.nih.gov/ncai/resources/docs/Technology\\_Readiness\\_Guidelines%20\(May2016\).xlsx](https://ncai.nhlbi.nih.gov/ncai/resources/docs/Technology_Readiness_Guidelines%20(May2016).xlsx)

If your technology does not fit into the NIH descriptions, please use a relevant adaptation.

Where possible you should pick the most closely related TRL category, but if you think that your technology doesn't fit within a TRL then please explain why.

### At the start of your project

Please explain why  
(50 words max.)

### Intended level at the end of the Innovator Award

Please explain why  
(50 words max.)

## Details of project

### Current status

**Please read guidance notes for details that must be included.**

Please give details of the scientific background to the project including, where appropriate, the validation of the therapeutic approach, target or technology solution (700 words maximum).

Describe:

- (a) the current stage of development of your IP/technology/approach
- (b) details of the evidence that provides validation of your proposal to date and the data that supports your technology, such as prototype design, biological data or chemical structures
- (c) the key assays and/or any other tools available to enable development of your proposal
- (d) the key risk-reducing steps to be addressed and overcome

*You may provide your answer to this question in text entry format or as a PDF attachment. If you are uploading your answer, the uploaded document must be in 11 point Arial font and portrait format. Please note that if you choose to upload a PDF it will not count as part of your five pages of optional additional information.*

*We will not be able to progress applications that do not address all parts of the question in full.*

*Please describe the work that has already been conducted and the current stage of development of your technology. Describe any proof-of-concept studies that have been conducted to support the validity of the proposed programme. Failure to provide supporting data will result in the application not being considered.*

*In addition, describe the available assays (and stage of development) or tools currently available to take the programme forward. This section should also describe the technical challenges to be addressed and overcome. Any claims related to the validation of the scientific approach should be supported by data which you can include in the additional information and/or references to publications.*

*For drug discovery proposals, the chemical matter, and its characterisation, is crucial to a thorough assessment of the opportunity by the Wellcome Trust. Chemical structures, if available, must be provided. Failure to do so will result in the application not being considered.*

The current status section must not exceed **700 words** and PDF submissions should conform to this guideline.

(700 words max.)

### **Project plan**

Define the primary objective of the proposal and briefly summarise the proposed project work plan (1000 words maximum).

Include:

- (a) the specific aims and objectives
- (b) a summary of expected deliverables of the project
- (c) a description of who will be involved in the project execution (including collaborators)
- (d) milestone criteria to be achieved by the end of the project
- (e) details of other resources to be leveraged against this application

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

*The specific aims and objectives of the proposed project should be clearly stated. A summary of expected deliverables of the project should also be provided in this section. You should describe who will be involved in the project execution and who will be doing key tasks. Include clear milestone criteria to be achieved by the end of the project. Please outline any other resources that will be leveraged against this application noting that this can include both cash and in-kind contributions. Where possible, provide a monetary value of the contribution.*

*Maximum **1,000 words**; PDF submissions should conform to this guideline. Please note that if you choose to upload a PDF it will not count as part of your five pages of optional additional information.*

*You must provide all information pertinent to your proposal within the application form (it is not acceptable to refer to additional unpublished information on personal websites).*

*Approach and methods to be used*

*Details of experimental design for animal studies should be provided as part of the justification for animals in the 'Costs requested and justification' section of the form.*

*For epidemiological, demographic, case control, cohort and related studies, give a full and detailed analysis of the study design, including details of any validation already undertaken or rationale for using standard protocols. Particular attention should be given to power calculations, sample size justification and, where appropriate, case definition and inclusion/exclusion criteria.*

(1000 words max.)

### **Competitive advantage**

Describe the competitive advantage of the proposed approach (500 words max.)

- Describe the competitive advantage of this technology over other research in the field, including an assessment of the advantages and disadvantages of competing technologies, both on the market and in development
- Include details of any previous attempts (either by yourself or others) against the same target or approach
- State the projected time to patient impact and how you will define this

### **Downstream strategy**

What are the subsequent development or implementation steps following this award?

Please consider the following:  
(a) who the downstream partner could be  
(b) what are the regulatory risks?  
(c) what is the likely clinical pathway?  
(d) what is your Target Product Profile (TPP)?  
(600 words max.)

Outline the downstream strategy taking the following into account, where appropriate:

- Who the downstream partner could be (which may include the technology being further developed by the applicant)
- What are the subsequent development steps that would need to take place before the technology could be taken to the market?
- What would the implementation strategy be, including delivery and market penetration?
- Are there any clinical, manufacturing, regulatory or marketing issues known that may affect the ability to deliver the product to market?
- If you have outlined any regulatory considerations or risks above, please show evidence that regulatory requirements are being accounted for in the product development
- For projects that do not include a clinical trial you should still outline the likely clinical pathway
- Please include the target product profile or key desired attributes of your healthcare innovation

### **Multidisciplinary collaborations**

If requesting support for a multidisciplinary collaboration, describe how your project brings together scientists from distinct scientific disciplines. Specify the individual contributions (including the key skills from each party) and the unique outcomes from the collaboration that would not otherwise be realisable.  
(300 words max.)

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 further information, refer to the Wellcome Trust's clinical trials policy statement.*

*If your proposal involves a clinical trial, you should provide details of it within this application form. If your proposal involves more than one clinical trial, please contact the Wellcome Trust for guidance.*

### **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.)

How do you propose to safeguard the privacy rights of data subjects?  
(100 words max.)

*Clinical trials can generate personal data that needs to be appropriately protected. It is important that the sponsor of the clinical trial is committed to complying with applicable law and has a practical plan of how to do so. This becomes more complex when clinical trials are multi-centre and/or multi-jurisdictional and managing privacy rights of trial participants should be considered as soon as possible. Please outline your plans to address this.*

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.)

### **Additional information**

You may submit up to five A4 pages of additional information (such as graphs, figures, tables and essential unpublished data).

*The additional information (such as graphs, figures, tables and essential unpublished data) provided in support of the proposal may be embedded in the text of your file upload or attached here as a separate file. If you choose to embed this information, any text present (such as legends, labels or captions) can be excluded from the word count.*

*Please note that this form asks for all the information we require to consider your application. You should not provide additional information (e.g. letters of support) unless specifically requested in the form.*

### **Gantt chart**

Please attach a Gantt chart or similar graphical overview of the tasks to be undertaken and their sequence and duration for the entire project. Please mark which tasks the Trust funding will be contributing to.

Provide a Gantt chart\* or similar graphical overview of the tasks to be undertaken and their sequence and duration for the entire project, including those (marked separately) that will be undertaken in parallel but without Trust funding (if applicable) and key development steps after Trust funding. What other external funds (if any) are contributing to related project tasks in the Gantt chart.

\*A Gantt chart is a project plan setting out the key tasks to be undertaken in parallel and sequentially together with timescales.

## References

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

You may provide up to the equivalent of two A4 pages of references. Please ensure that all references included 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. References with more than 10 authors may be shortened to et al, but please ensure that your position as author (if applicable) remains clear. Citations to preprints should state "Preprint", the repository name and the article persistent identifier (e.g DOI).

You may refer to papers "in press"; copies of these papers should be submitted. Manuscripts that are "in preparation" or "submitted for publication" must not be included in the reference list, but key data from these papers may be included as "additional information".

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

Upload papers "in press"

Please submit papers "in press" as a single PDF.

## Patent information

### Patent information

Please provide a summary describing the current patent status, if any. Please note if any patentable inventions might arise during the proposed project.

Please provide details of all patent applications/intellectual property protection filed before the date of this application that relate directly to the project outlined. State the funding sources that have contributed to the development of the protected technology (e.g. company collaboration, research council and/or charity funding).

If not relevant at this stage, enter N/A.

### Intellectual property and freedom to operate

Is the proposed research, in whole or in part, subject to any legal agreements with commercial, academic or other organisations that could present a freedom to operate problem in the future?

With reference to the intellectual property information provided, as appropriate:

- summarise the inventive step and key claims of patents, patent applications or other protections relating to the technology that have already been filed
- consider whether there are any freedom to operate issues in the area of the proposed technology and consider how these will be addressed during the project
- explain how the proposed experiments will add value to or strengthen an existing intellectual property position
- explain the novel and inventive aspects of the Innovator Award project being proposed for funding
- outline any likely new intellectual property that may arise from this project and set out the main areas of likely

claims.

If not relevant at this stage, enter N/A.

## Outputs management and sharing

Will the proposed research generate outputs of data, software, materials or intellectual property that hold significant value as a resource for the wider research community?

As set out in our *Data, Software and Materials Management and Sharing Policy*, 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. If your proposed research is likely to generate significant outputs - data, software, materials and/or intellectual property - that will hold clear value as a resource for others in academia or industry, you are required to provide an outputs management plan.

Our guidance on developing an outputs management plan sets out the circumstances under which such a plan is required and gives an overview of what you should consider.

Your plan should be clear, concise, proportionate and focus specifically on how outputs will be identified, managed and then used to advance potential health benefits. You should set out and address clearly the following:

1) For significant data, software and materials outputs

- (i) What significant outputs will your research generate?
- (ii) When do you intend to share these outputs?
- (iii) Where will you make these outputs available?
- (iv) How will they be discovered and accessed by others?
- (v) Are limits on sharing required?
- (vi) How will these outputs be preserved?

2) For intellectual property outputs

- (i) What IP will your research generate?
- (ii) How will you protect this IP?
- (iii) How will the IP be used to achieve health benefits?
- (iv) Provide the name and contact details for the person in your organisation (e.g. Technology Transfer Officer or Business Development executive) who can act as a point of contact for Wellcome in connection with the protection and commercialisation of this IP.

3) Describe any resources that you will need to deliver your outputs management plan.

Please note that regardless of whether or not a plan is required, you must ensure that data and original software underlying published research findings are accessible at the point of publication.

Which approach do you intend to use to maximise the impact of your significant research outputs to improve health and benefit the wider research community?

Please provide an outputs management plan. Ensure this describes any significant data, software, materials or intellectual property outputs, their management, and resources required (refer to guidance).

(700 words max.)

Please refer to guidance for the above question: 'Will the proposed research generate outputs of data, software, materials or intellectual property that hold significant value as a resource for the wider research community?'

## Public engagement

Do you have plans for engaging with the non-academic public about your work?

*The Wellcome Trust is committed to engaging with society about the research it supports. We aim to foster mutual trust and understanding and place science within a societal, historical and cultural context. Further information is available on the Wellcome Trust's website.*

*We expect those researchers who receive funding from the Wellcome Trust to help support an environment within which science can flourish by informing, consulting and collaborating with the non-academic public.*

Please provide a brief outline of your public engagement plans. (250 words max.)

*Describe your plans to engage the non-academic public about your work beyond press and media activity. Engagement that is essential for the ethical conduct of the research, such as patient information leaflets or community advisory boards, should be part of your research methodology and included within your main research costs.*

Please note that we provide support for Wellcome Trust funded researchers to engage with the non-academic public. Do you wish to receive information about training, funding and other public engagement opportunities?

## Location of activity

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

*It is important that we are able to track the countries and organisations where research activity is taking place and the approximate proportion of the funds that will be spent at each location.*

*You should list any locations where you will be conducting research or redirecting funds outside of the administering organisation. This includes, but is not limited to, anywhere in receipt of indirect funding, fieldwork sites, and time spent working in another institution/laboratory. This does not include conference attendance.*

*Salary costs, if requested, should be attributed to the employing organisation.*

For each location, select the country and, where applicable, state the organisation (please include the administering organisation). Indicate the approximate percentage of the total funds that will be spent in each location, entering zero for locations where activity will take place but no significant funds will be spent. Salary costs, if requested, should be attributed to the employing organisation.

| Country | Organisation | Percentage of funds |
|---------|--------------|---------------------|
|         |              |                     |

## Costs requested and justification

Please select the currency in which you wish to apply.

*It is expected that costs within the application will be submitted in the currency which, in the view of the applicant(s), best*

enables the activity to be undertaken. In the majority of cases, the currency specified is likely to be the local currency. Where this is not the case, please explain the reasons for selecting the chosen currency.

Please refer to the Wellcome Trust's website for further information regarding selecting a currency.

If at any point, the Wellcome Trust is unable to award in the currency requested, discussions will be held with the administering organisation to decide whether an alternative currency should be used. If you have any concerns that the currency you would like to request may not be readily available, please contact the Wellcome Trust by e-mailing: [grantpayments@wellcome.ac.uk](mailto:grantpayments@wellcome.ac.uk).

Is the selected currency your local currency?

What is your local currency?

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

### Salaries

Are you requesting salaries?

Please refer to guidance notes and definition of terms for further details.

Please include the full employment costs for all staff requested. In most cases, requests to cover a postdoctoral salary for carrying out some work at a company will be considered.

The names of individuals for posts involving the handling of and research on non-human primates should be provided. Once an application has been submitted, the Wellcome Trust must be notified of any change to the individual(s) named in the application, prior to it being considered.

#### Definition of terms

**Staff category:** For example: "Postdoctoral research assistant", "Technician", "Fieldworker".

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

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

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

### Salaries / Stipends

| Staff category | Name (if known) | Basic starting salary (p.a.) | Salary grade / scale | Period on project (months) | % time | Total |
|----------------|-----------------|------------------------------|----------------------|----------------------------|--------|-------|
|                |                 |                              |                      |                            |        |       |

### Materials and consumables

Are you requesting materials and consumables?

## Materials and consumables

| Description | Total |
|-------------|-------|
|             |       |

|   |  |
|---|--|
| <b>Animals</b>  |  |
| Are you requesting animals?   |  |
| <p><i>In order to ensure animal experimentation costs are accurate, applicants are advised to complete this section after consultation with their animal house or biological services manager. The organisation is required to apply a consistent costing methodology when presenting cost details to the Wellcome Trust.</i></p> <p><i>If appropriate, costings can be clarified in more detail in the 'Justification for resources requested' section of the form.</i></p> <p><i>The Trust reserves the right to ask for more detailed costing information from the organisation where a large number of animals and/or substantial costs are involved.</i></p> |  |

## Animals

| Animal species | Total no. to be purchased | Total purchase cost | Total maintenance and procedures cost | Total |
|----------------|---------------------------|---------------------|---------------------------------------|-------|
|                |                           |                     |                                       |       |

## Associated animals costs

| Description  | Total |
|--|-------|
|  |       |
| <p><i>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.</i></p> |       |

|  |  |
|--|--|
| <b>Equipment</b>   |  |
| Are you requesting equipment or equipment maintenance?   |  |
| <p><i>The organisation's Director of Procurement/Head of Purchasing (or equivalent) should be aware of all potential capital purchases and the organisation is required to use best procurement practice when purchasing equipment funded with Wellcome Trust funds.</i></p> <p><b>Equipment to be purchased</b></p> <p><i>The Trust expects applicants to consider the cost-effectiveness of the proposed purchase of equipment. The estimated price of the equipment should cover all aspects including delivery, installation, maintenance and training, where appropriate. Discounted prices should be quoted wherever possible. A copy of at least one formal quote is required for each piece of equipment with a list price of £100,000 or more. The level of discount that has been negotiated should be clearly stated in the quote.</i></p> <p><i>A contribution from the host organisation, or other source, will normally be expected where the application includes a substantial equipment request. Please refer to the scheme webpage for further details.</i></p> <p><i>If applicants have a preferred manufacturer for certain items of equipment, they are able to enter this detail in the 'Type of equipment' field.</i></p> <p><i>It is expected that the equipment requested will be covered by the manufacturer's warranty for the first year after it is purchased. The Wellcome Trust will fund reasonable maintenance costs for four years after the initial period of warranty on all equipment (irrespective of the length of award made), where this is negotiated as part of the capital purchase cost. In cases where support is being requested for a period greater than 60 months, consideration will be given to providing maintenance funds for equipment more than five years old only if the applicant can demonstrate that it is cost-effective to do so.</i></p> |  |

**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 should be quoted exclusive of VAT. For equipment that does not fall within this definition, VAT costs should be shown.

**Equipment**

| Type of equipment | No. of items | Cost per item | Cost of maintenance contract | Contribution from other sources | Total |
|-------------------|--------------|---------------|------------------------------|---------------------------------|-------|
|                   |              |               |                              |                                 |       |

**Maintenance for existing equipment**

| Details of equipment/ facility | Wellcome Trust grant number | Date of purchase | End date of current contract | Total cost of contract | % time on project | Total |
|--------------------------------|-----------------------------|------------------|------------------------------|------------------------|-------------------|-------|
|                                |                             |                  |                              |                        |                   |       |

Requests for maintenance of existing equipment may be considered if the original grant period has ended. For equipment more than five years old, maintenance costs will be provided only if it is cost-effective to keep maintaining it.

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

Please upload a copy of at least one formal quote

If there is more than one quote, please submit these as a single PDF.

**Synchrotron radiation sources**

Will the proposed research require access to a synchrotron source?

We wish to collect data on access to synchrotron sources for information purposes.

Applicants should apply directly to the synchrotron facility they wish to use. These facilities are normally free at the point of access for researchers who are prepared to publish their results in the public domain. If this is not the case for the facility that you have selected, access costs may be requested from the Wellcome Trust.

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

Please specify:

Are you requesting costs from the Trust?

These facilities are normally free at the point of access for researchers who are prepared to publish their results in the public domain.

In instances where the costs of travel and subsistence will not be met by the facility, they may be requested from us. Please provide details of these costs in the 'Travel and subsistence' costs section.

|  |  |
|--|--|
| <b>Access charges</b><br>Are you requesting access charges?                            |  |
| <i>Please refer to the scheme webpage for information on allowable access charges.</i> |  |

### Access charges

| Details of equipment/facility | Original source of funding | Wellcome Trust grant number, if applicable | Standard access charge per unit | Specify unit | No. of units to be used for this project | Total |
|-------------------------------|----------------------------|--|---------------------------------|--------------|--|-------|
|                               |                            |  |                                 |              |  |       |

|  |  |
|--|--|
| <b>Travel and subsistence</b><br>Are you requesting travel and subsistence?  |  |
| <p><i>Items that should be detailed here can include conference attendance and collaborative visits. Where necessary, please state the host organisation.</i></p> <p><i>Conference attendance</i><br/>For applications from Universities, not-for-profit organisations and SMEs: costs to attend academic/scientific conferences, including conference registration fees, may be requested for the Lead Applicant and any research staff to be employed on the grant, up to the maximum annual amount specified on the scheme webpage. These costs may also be requested for Applicants seeking their own salary on the grant. Please specify the amount being requested per person.</p> <p><i>Collaborative visits</i><br/>Where any costs for collaborative visits are requested, please state the host organisation and provide a detailed breakdown of the travel and subsistence costs. The need for the visit, and its duration, must be justified in the application.</p> |  |

### Travel and subsistence

| Description | Total |
|-------------|-------|
|             |       |

|  |  |
|--|--|
| <b>Contract research organisation costs</b><br>Are you requesting contract research organisation costs?  |  |
| <p><i>Where there is requirement for a project to outsource certain elements of the work to contract research organisations, please provide a breakdown of these costs.</i></p> <p><i>Where possible, please include quotes with the application.</i></p> <p><i>The applicants, through their Technology Transfer Officer (or equivalent), will be responsible for the arrangements made with outsource suppliers. Such arrangements must be on a value for money, fee-for-service basis, and should not involve intellectual property sharing or joint-ownership unless such arrangements have been specifically agreed with the Wellcome Trust. Both background and arising intellectual property must be free of encumbrance for translation.</i></p> |  |

### CRO costs

| Description | Total |
|-------------|-------|
|             |       |

Please upload any quote(s) for contract research organisation costs as a single PDF.

|                            |  |
|----------------------------|--|
| <b>Miscellaneous costs</b> |  |
|----------------------------|--|

Are you requesting miscellaneous costs?

*We require a detailed breakdown of the miscellaneous costs requested. Costs that do not fall under any other category should be entered in this section. These may fall under specific subheadings (such as 'Overseas allowances'); where they do not, please select 'Other' and type a description of the item.*

**Research management and support costs**

*Where research management and support costs are allowed and are being requested, a full cost breakdown must be provided, together with a letter from the Finance Director of the host organisation confirming that the request is a true representation of the costs incurred.*

**Working abroad**

*If costs are requested for the applicant(s), and/or research staff to be employed on the grant, to carry out part of the proposed research abroad, please state the overseas host organisation, and detail the travel costs, and any overseas allowances requested. Further guidance can be found on the scheme webpage.*

**Miscellaneous other**

| Type | Description | Total |
|------|-------------|-------|
|      |             |       |

**Justification for resources requested**

Please provide a complete justification for all the resources requested, ensuring that you present this information according to the cost headings requested above.  
(1000 words max.)

*You should present the justification according to the high-level cost headings in this form, e.g. "Salaries"; "Materials and consumables"; "Miscellaneous".*

*Where staff requested will be working in different locations, please indicate where they will be working.*

*Please provide a justification for all animal and animal associated costs. This does not need to include a justification of the animal numbers required, which can instead be included in the 'Proposals involving animals' section.*

*Please include justification of the need for any collaborative/overseas visits and their duration.*

**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 (£)? |  |
|---|--|

*Please provide the **total** full economic cost of your research proposal. Costs should be inflated at the recognised percentage rate currently used by the organisation.*

## Research involving human participants, human biological material and identifiable data

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

*The following notes relating to 'Research involving human participants, human biological material and identifiable data' 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.*

*The World Health Organization defines research with human subjects as "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 i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or ii) become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records."*

*The Wellcome Trust policy position on research involving human participants can be found on the Wellcome Trust website ([www.wellcome.ac.uk/wellcome-trust-policy-position-research-involving-human-participants](http://www.wellcome.ac.uk/wellcome-trust-policy-position-research-involving-human-participants)).*

*Ethical approval (usually from the appropriate National Health Service (NHS) research ethics committees) is required for all Wellcome Trust funded research involving human participants, biological samples or personal data. Personal data, in the context of the 1998 Data Protection Act (Section 3.2, and Annex 3), comprise information about living people who can be identified from the data, or from combinations of the data and other information which the person in control of the data has, or is likely to have in future. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available at: <http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/> and <http://www.insight.mrc.ac.uk/2015/02/12/getting-the-best-out-of-biological-samples/>.*

*Approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority (HFEA) or the Gene Therapy Advisory Committee in the UK should also be sought where necessary, e.g. research involving human embryos may require a licence from the HFEA (please refer to [www.hfea.gov.uk](http://www.hfea.gov.uk) for more information). If your proposal involves research on gene therapy which requires regulatory approval, approval should be sought from your Local Research Ethics Committee, the University's Genetic Manipulation Committee, the Gene Therapy Advisory Committee and the Medicines and Healthcare products Regulatory Agency (MHRA).*

*The organisation must ensure that ethical approval is in place at all relevant times during the project. For research carried out at multiple sites, ethics committee approval must cover each site.*

*Where the research, or part of the research, is to be performed outside the UK, independent ethics review must be obtained. For research involving people living in low and middle income countries, see the Wellcome Trust's website ([www.wellcome.ac.uk/funding/managing-grant/guidance-notes-research-involving-people-low-and-middle-income-countries](http://www.wellcome.ac.uk/funding/managing-grant/guidance-notes-research-involving-people-low-and-middle-income-countries)).*

|   |
|---|
| 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. |
|   |

*The Wellcome Trust's guidelines on the feedback of health-related findings in research can be found on the Trust's website.*

|   |
|---|
| 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. |
|---|

|   |
|---|
| <i>The following notes relating to 'Research involving human participants, human biological material and identifiable data' are intended to provide guidance and advice in completing the form, rather than a comprehensive review of the legal and</i> |
|---|

regulatory environment in which the application is made.

*The World Health Organization defines research with human subjects as "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 i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or ii) become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records."*

*The Wellcome Trust policy position on research involving human participants can be found on the Wellcome Trust website ([www.wellcome.ac.uk/wellcome-trust-policy-position-research-involving-human-participants](http://www.wellcome.ac.uk/wellcome-trust-policy-position-research-involving-human-participants)).*

*Ethical approval (usually from the appropriate National Health Service (NHS) research ethics committees) is required for all Wellcome Trust funded research involving human participants, biological samples or personal data. Personal data, in the context of the 1998 Data Protection Act (Section 3.2, and Annex 3), comprise information about living people who can be identified from the data, or from combinations of the data and other information which the person in control of the data has, or is likely to have in future. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available at: <http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/> and <http://www.insight.mrc.ac.uk/2015/02/12/getting-the-best-out-of-biological-samples/>.*

*Approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority (HFEA) or the Gene Therapy Advisory Committee in the UK should also be sought where necessary, e.g. research involving human embryos may require a licence from the HFEA (please refer to [www.hfea.gov.uk](http://www.hfea.gov.uk) for more information). If your proposal involves research on gene therapy which requires regulatory approval, approval should be sought from your Local Research Ethics Committee, the University's Genetic Manipulation Committee, the Gene Therapy Advisory Committee and the Medicines and Healthcare products Regulatory Agency (MHRA).*

*The organisation must ensure that ethical approval is in place at all relevant times during the project. For research carried out at multiple sites, ethics committee approval must cover each site.*

*Where the research, or part of the research, is to be performed outside the UK, independent ethics review must be obtained. For research involving people living in low and middle income countries, see the Wellcome Trust's website ([www.wellcome.ac.uk/funding/managing-grant/guidance-notes-research-involving-people-low-and-middle-income-countries](http://www.wellcome.ac.uk/funding/managing-grant/guidance-notes-research-involving-people-low-and-middle-income-countries)).*

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 (which will normally be either a university or NHS Trust) who fully understands the responsibilities and costs associated with assuming this role. Please note that the Wellcome Trust cannot act as sponsor.*

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?

*By agreeing to fund work which requires NHS support, the Wellcome Trust is agreeing 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). Researchers 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 <http://www.dh.gov.uk/health/category/research>. Please note that the Wellcome Trust cannot act as sponsor.*

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.

Please answer 'not applicable' if no potentially commercially exploitable results (based on human tissues or samples) will be produced during the course of the proposed research.

## 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)

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 the Wellcome Trust's policy on the use of animals in medical and veterinary research on the Trust's website.

In all animal experiments supported by the Wellcome Trust, the principles of reduction, replacement and refinement will apply. In all experimental studies, it is the responsibility of the applicants to 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 in order 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, and/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;
- the experimental design (e.g. the choice of species and the group size employed);
- the techniques applied;
- the end points of the procedures; and
- care of the animals before, during and after a procedure.

For further information regarding the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), please see [www.nc3rs.org.uk](http://www.nc3rs.org.uk)

### Monoclonal antibodies

The use of ascitic animals for monoclonal antibodies (mAb) production in vivo should 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. If in vitro production methods are not considered to be suitable, a full explanation must be given.

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

All applications involving the use of primates, cats, dogs and equidae animals, or their tissue/data will be further reviewed

by the NC3Rs.

All proposed research projects involving genetically altered mice are expected to consider the principles of welfare assessment set out on the NC3Rs website: <https://www.nc3rs.org.uk/generation-and-breeding-genetically-altered-mice>.

Click 'Add...' to enter details of the animal species and numbers required

| Animal species | Strain (if appropriate) | Total number required to carry out proposed work |
|----------------|-------------------------|--|
| -              |                         |  |

Please provide details on any animal species which are to be used in the proposed project. Please provide the total number to be used (this may differ from the number to be purchased, maintained etc.)

Please justify the animal numbers. A justification of the proposed sample size must be given along with details of the planned statistical analyses. Describe experimental design, including any plans to reduce bias such as blinding or randomisation if appropriate. Power calculations must be included in this section if appropriate. (1,000 words max.)

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

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

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

Tables and figures may be included in this section to help justify animal numbers. For additional guidance on designing animal experiments please see the NC3Rs Experimental Design Assistant: <https://www.nc3rs.org.uk/experimental-design-assistant-eda>

(1000 words max.)

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

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

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

The organisation must ensure that research involving the use of animals complies at all times with UK laws and regulations.

If your proposal involves the use of animals, what would be the severity of the procedures?

Guidance on assessing the severity of a procedure is available from the Home Office website: <http://www.homeoffice.gov.uk/science-research/animal-research/>

Please provide details of any moderate, severe or non-recovery procedures (250 words max.)

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

Animal research conducted outside the UK must, as a minimum standard, be carried out in accordance with the principles of UK law and regulation. Please confirm that proposed animal work outside of the UK will comply with these principles. (1000 words max.)

*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 accord with the principles of UK legislation. Furthermore, the housing and care of animals must similarly accord with the standards and principles of UK legislation.*

*Please refer to NC3Rs guidance on carrying out work abroad and choosing contractors:  
<https://www.nc3rs.org.uk/news/choosing-contractors-animal-research>*

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

*Please specify if there are any other procedures of less severity that could be used and how the 3Rs have been implemented.*

### Non-human primates

*If you are exclusively using already generated tissue or data in the proposed experiments please answer all relevant questions as thoroughly as possible, in particular the questions relating to housing and procedures. Non-relevant questions can be answered with 'N/A', but please note that we may request additional information if necessary for assessment.*

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: 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.

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

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| 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. |
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| 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 Animal Welfare and Ethical Review Body (AWERB)? |
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| Will any of the experimental procedures involve food and/or water restriction? |  |
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| Justify why this is necessary and outline what alternatives have been considered. |
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| Will any of the experimental procedures involve restraint? |  |
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| What alternatives have been considered? Describe the nature of the restraint, its duration and frequency, and what will be done to avoid distress. |
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| 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? |
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| Will any of the staff involved require specific training for any of the procedures concerned? |  |
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| Please provide details of the training needed and where it will be undertaken. |
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**Cats, Dogs, Equidae and Pigs**

*If you are exclusively using already generated tissue or data in the proposed experiments please answer all relevant questions as thoroughly as possible, in particular the questions relating to housing and procedures. Non-relevant questions can be answered with 'N/A', but please note that we may request additional information if necessary for assessment.*

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| From where will the animals be sourced? |
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| Will it be necessary to transport the animals? |  |
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Indicate approximate journey times and the measures that will be taken to minimise the potential stress during transport.

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| Are animals to be imported? |  |
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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.

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

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*Please see the NC3Rs guidance on animal housing and husbandry for further details: <https://www.nc3rs.org.uk/3rs-resources/housing-and-husbandry>*

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

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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 Animal Welfare and Ethical Review Body (AWERB)?

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What adverse effects might the animals experience? List the clinical and other signs that will be monitored, the frequency of monitoring and, where relevant, the humane endpoint criteria established for the study.  
(1000 words max.)

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| Will any of the experimental procedures involve restraint? |  |
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What alternatives have been considered? Describe the nature of the restraint, its duration and frequency, and what will be done to avoid distress.

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| What prior experience and training in animal use, care and welfare will be required of the staff |
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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

*In preparing research proposals, Wellcome wishes to encourage applicants and their host organisations to consider carefully any risks that the potential outcomes (information, products or technologies) of the research could be misused for harmful purposes. Such purposes would include actions that pose a significant threat to humans, animals, plants or the environment - including terrorist misuse.*

*Examples of possible research areas that are associated with dual-use risks of this type, include (but are not restricted to) research that aims to:*

- 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

*Where there are judged to be **tangible** (i.e. real and non-hypothetical) risks that the proposed research **will itself** generate outcomes that could be misused to cause harm, researchers and organisations should 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. Researchers should also ensure that all members of their team are aware of these risks in progressing their research, and receive appropriate education and training on these issues.*

*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. We recognise that most research could conceivably generate results that might hypothetically be misused at some point in the future, and we are not asking applicants to appraise these kinds of remote and hypothetical risks.*

*Applicants should refer to the joint BBSRC, MRC and Wellcome policy and position statement on managing risks of research misuse (<https://wellcome.ac.uk/funding/managing-grant/managing-risks-research-misuse>), and our guidelines on good research practice (<https://wellcome.ac.uk/funding/managing-grant/policy-good-research-practice>).*

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.)

## 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
- an Africa and Asia Programme
- the Francis Crick Institute?

*We are interested to find out about Trust-funded projects based in these facilities and wish to collect this data for information purposes.*

Please specify

Sample