Application summary

Type of award Please select the type of award you are applying for

Application title
This should be the title of your proposal.

Proposed duration of funding (months)

Proposed start date	
You should allow at least six months between the submission of your application and the proposed starting date.	

Name of administering organisation
Please enter the name of the organisation where you intend to hold the award. 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 address where you will be working at the administering organisation. If your application is successful, this is the address that will be used in the award letter.	

Summary of support sought (30 words max.)

Research funding area Please select from the drop-down list the funding area that you consider your research falls under

The research funding area selected is used to automatically route your application form to the appropriate Wellcome Trust grants team when it arrives at the Trust. Please note that, when received, we may reallocate your application to another research funding area if we consider it appropriate.

Is this an application for a resource previously funded by Wellcome?	

Lead applicant

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

A maximum of ten applicants is permitted, i.e. Lead applicant plus up to nine other applicants. For the purpose of this application, the co-ordinating applicant will be lead applicant.

For multi-user equipment applications, additional researchers may be listed in the 'Details of resource, technology development or equipment' section, together with details of their need for the equipment.

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.

Source(s) of personal salary support

Your source of salary may have an impact on your eligibility to apply for Wellcome Trust funding. Please, therefore, state the source of funding of the salary of your post (for example, if it is 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'.

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.

Please provide details

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.

Details of any relevant previous experience of managing a resource, a technology or equipment. (350 words max.)

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

The examples you choose can be taken from any stage of your research career. In each case, please state what the achievement was, when it came about, why you think it is important and what impact it has had.

Research outputs
List up to 20 of your most significant research outputs, ensuring that at least five of these are from the last five years. For 10 of these outputs, provide a statement describing their significance and your contribution (up to 50 words per output).

Research outputs may include (but are not limited to):

- Peer-reviewed publications and preprints
- Datasets, software and research materials
- Inventions, patents and commercial activity

For original research publications indicate those arising from Wellcome funded grants in **bold**, and provide the PubMed Central ID (PMCID) reference for each of these. Please refer to guidance notes.

Please give citation in full, including title of paper and all authors. Citations to preprints should state "Preprint", the repository name and the articles persistent identifier (e.g. DOI).*

*(*All authors, unless more than 10, in which case please use 'et al', ensuring that your position as author remains clear.)*

You should include here systematic reviews (e.g. Cochrane Reviews) and meta analyses, but exclude abstracts and literature reviews. We encourage the inclusion of articles published via open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.

Preprints, i.e. complete manuscripts that have been submitted to a preprint repository or service (e.g. bioRxiv, PeerJ Preprints, arXiv, SocArXiv or PsyArXiv), can be included only if they have a permanent identifier such as a DOI or arXiv identifier.

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

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

You should include here systematic reviews and meta analyses. We encourage the inclusion of articles published via open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.

Current research funding (including Wellcome Trust grants) Please list all active grants only (starting with the most recently awarded). State the name of the awarding body, name(s) of grantholder(s), title of project, amounts awarded, your role in the project, and start and end dates of support. Indicate the number of hours per week that are spent on each project.
Success in obtaining funding for your research forms part of the assessment of your track record. In addition to research grants, please include details of any recurrent or core funding support that you currently hold, including any Wellcome Trust awards. Please state clearly your role in obtaining the awards, for example, whether you hold them in your own right as lead applicant, co-applicant, or as part of a consortium. Please state the value of your own component of the award and the percentage of your time spent on the research.

Please describe how the currently active grants listed above relate to this application (200 words max.)

Time spent on research How many hours per week do you spend on research?

How many hours per week will be spent on this project?

Applicants

An applicant is someone who has significant input into the project.

A maximum of ten applicants is permitted, i.e. Lead applicant plus up to nine other applicants.

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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**

An applicant is someone who has significant input into the project.

Source(s) of personal salary support

Your source of salary may have an impact on your eligibility to apply for Wellcome Trust funding. Please, therefore, state the source of funding of the salary of your post (for example, if it is 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'.

Details of any relevant previous experience of managing a resource, a technology or equipment. (350 words max.)

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

The examples you choose can be taken from any stage of your research career. In each case, please state what the achievement was, when it came about, why you think it is important and what impact it has had.

Research outputs
List up to 20 of your most significant research outputs, ensuring that at least five of these are from the last five years. For 10 of these outputs, provide a statement describing their significance and your contribution (up to 50 words per output).

Research outputs may include (but are not limited to):

- Peer-reviewed publications and preprints
- Datasets, software and research materials
- Inventions, patents and commercial activity

For original research publications indicate those arising from Wellcome funded grants in **bold**, and provide the PubMed Central ID (PMCID) reference for each of these. Please refer to guidance notes.

Please give citation in full, including title of paper and all authors. Citations to preprints should state "Preprint", the repository name and the articles persistent identifier (e.g. DOI).*

*(*All authors, unless more than 10, in which case please use 'et al', ensuring that your position as author remains clear.)*

You should include here systematic reviews (e.g. Cochrane Reviews) and meta analyses, but exclude abstracts and

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

Preprints, i.e. complete manuscripts that have been submitted to a preprint repository or service (e.g. bioRxiv, PeerJ Preprints, arXiv, SocArXiv or PsyArXiv), can be included only if they have a permanent identifier such as a DOI or arXiv identifier.

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

You should include here systematic reviews and meta analyses. We encourage the inclusion of articles published via open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.

Current research funding (including Wellcome Trust grants)
Please list all active grants only (starting with the most recently awarded). State the name of the awarding body, name(s) of grantholder(s), title of project, amounts awarded, your role in the project, and start and end dates of support. Indicate the number of hours per week that are spent on each project.

Success in obtaining funding for your research forms part of the assessment of your track record. In addition to research grants, please include details of any recurrent or core funding support that you currently hold, including any Wellcome Trust awards. Please state clearly your role in obtaining the awards, for example, whether you hold them in your own right as lead applicant, co-applicant, or as part of a consortium. Please state the value of your own component of the award and the percentage of your time spent on the research.

Please describe how the currently active grants listed above relate to this application (200 words max.)

Time spent on research
How many hours per week do you spend on research?

How many hours per week will be spent on this project?

Applicant details summary
Please also complete brief summary details for the lead applicant and each applicant listed above.

Name	**Organisation**	**Role in project**

This is to provide Wellcome with an overview of the applicants and their involvement in the programme.

Collaborators

Will you require any key collaborators for this proposal?	

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

are not involved in the day-to-day execution of the project.

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 activity.

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

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

Related applications

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

The Wellcome Trust will consider this application even if the same or a similar application is currently under consideration elsewhere. However, if offered such an award by another funding body whilst the application to the Trust is being considered, you are required to inform us immediately of the offer and will normally be required to take a decision on that offer of award within one month.

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.

Please note that applicants applying for a multi-user equipment grant where a significant proportion of users of the equipment are not Trust-funded are expected to consider seeking an appropriate financial contribution from alternative sources, including other funding bodies. Please contact the Wellcome Trust to discuss any related applications for contributions from other funding sources before submitting your Trust application.

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

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

Applicants must contact the Wellcome Trust before resubmitting an application.

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

Summary of proposal

Proposal summary
Please provide a summary of your proposal, including key goals, for an expert audience

(200 words max.)

Please provide a summary of your proposal, aimed towards an expert audience. This will be used as a short form 'abstract' and is necessary to enable the Trust to classify your proposal by subject area. This synopsis may be disclosed on the Wellcome Trust website and may be used for other publishing purposes. For all our awards, we publish the synopsis as part of the grant details made available externally.

The summary should be as complete as possible within the word limit, and should include key words which best describe the proposal to enable text searching.

Lay summary
Please provide a summary of your proposal that people who may not be familiar with the subject can understand. We may edit your summary and then use it to describe your research on our website and elsewhere.

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:

- *background to the research problem*
- *your approach*
- *expected impact of your work.*

Example of a lay summary
In response to stress and environmental changes, bacteria generate hundreds of small RNA molecules that have key roles in regulating gene expression. This process of riboregulation involves chaperone proteins that facilitate the actions of regulatory RNAs, and enzymes that affect RNA transcript lifetimes. I aim to understand the molecular basis of riboregulation by taking a multidisciplinary approach. I will use biochemical and structural analyses, including cryoEM and cryoET, to visualise how RNA transcripts are captured and channelled to active sites, either for degradation or processing. I will also identify the RNA targets of chaperone proteins and the degradative machinery, and explore whether the patterns change with physiological state or during the cell cycle, and why. These studies will help to explain how small RNAs enhance the speed and accuracy of bacterial genetic regulation, enriching the capacity of the simplest organisms to exhibit complex behaviour.

Resources previously funded by Wellcome

Please describe the progress, achievements etc. since the last funding round
(500 words max.)

Details of resource, technology development or equipment

For Biomedical Resource and Technology Development applicants only:

Please describe (i) the resource or technology development requested; (ii) the 'added value' it will bring; (iii) the community need for the resource or technology development (please upload letters of support and make reference to the availability of similar resources/technology, if appropriate); (iv) how the resource or technology development will enhance the scientific programmes of the applicants and/or the research community; (v) the approach and methods to be used to create the resource or to develop the technology, including timetable and milestones (indicating any relevant

information from your business plan for developing long-term financial sustainability, if appropriate); (vi) plans for promoting and/or disseminating the resource or technology development; (vii) the regional, national (and international, if appropriate), context of the application, including any joint funding arrangements; (viii) any relevant background information.

*No more than **3,000 words** should be used to describe the proposal, excluding graphs, figures, references, letters of support, etc. You may provide your answer 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.*

Graphs, figures and essential quoted but unpublished information, such as pilot data, provided in support of the proposal, may be embedded in the text or attached as supporting material - this must not exceed the equivalent of two A4 pages in length.

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

Describe the potential added value and impact of the resource or technology development for your research and, if relevant, the wider scientific community. Will the gains be in increased efficiency or in new research capabilities? How important is the research that will benefit? Please ensure that letters of support provided by user communities detail specifically how the resource or technology will be used by the group to enhance their research outputs.

Evidence of demand for the resource or technology should be included, together with details of consultations with user (or potential user) communities. Supporting statements from any user communities (including potential users) may be uploaded in a single PDF file under the 'Letters of support' section.

Provide details of how the resource or technology will be established and/or maintained, including plans for promotion and/or dissemination.

(3000 words max.)

For Multi-user Equipment applicants only:

Please describe (i) the equipment requested including a scientific justification for the type and model; (ii) details of the research projects that will benefit from the equipment, how they are funded, and how the equipment will enhance the scientific outputs of the projects; (iii) details of similar equipment in the applicants' departments and adjacent departments and the reasons why it cannot be used for the purposes described; (iv) details of others who may benefit from the requested equipment; (v) the regional, national (and international, if appropriate), context of the application, including any joint funding arrangements; (vi) any relevant background information.

*No more than **3,000 words** should be used to describe the proposal, excluding graphs, figures, references, letters of support, etc. You may provide your answer 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.*

Graphs, figures and essential quoted but unpublished information, such as pilot data, provided in support of the proposal, may be embedded in the text or attached as supporting material - this must not exceed the equivalent of two A4 pages in length.

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

Describe the potential added value and impact of the equipment for your research and, if relevant, the wider scientific community. Will the gains be in increased efficiency or in new research capabilities? How important is the research that will benefit? Please ensure that letters of support provided by user communities detail specifically how the equipment will be used by the group to enhance their research outputs. Please include an indication as to the amount of time each user group anticipate will be spent with the equipment requested.

(i) Pilot data may be provided to support the type and model of equipment requested, if available. These may be embedded in the text of the proposal, or attached separately as supporting material.

(ii) Please state whether funding for the research projects described has been obtained and, if so, include the name of the funding organisation, the amount, duration and nature of the funding. Please note research that has not yet been

funded through a peer review process is unlikely to present a compelling case for funding of major items of equipment.

(iv) Brief curricula vitae (maximum two pages) of any additional individuals who will make use of the equipment, and are mentioned in the application, should be provided. This information may be attached as an appendix.

(3000 words max.)

For Longitudinal Population Study applicants only:

Outline the community need and value of the resource
If applying for core support for an LPS, please describe how it meets the quality criteria. Refer to guidance.
If applying for enabling structures for LPS, please describe how it maximises the value of LPS and/or their data.
(3000 words max.)

*The quality criteria for LPS **core support**, along with associated metrics, are detailed below. Existing core resources should report on how well the LPS meets the metrics associated with each criteria. New core resources should describe how they will meet these criteria.*

Criterion 1: A clear vision with unique scientific impact and potential - relating broadly to human health

- *Describe the evidence that the LPS is, or will be, a valuable resource for the wider community, and outline how it is or will become a robust, cost-effective, and innovative way of answering a range of important research questions*
- *A clear strategy outlining potential pathways to future impact*
- *For existing resources: describe the main impacts of the resource, which may be unique scientific findings, impact on policy and practice, or developing new scientific techniques.*

Criterion 2: Robust leadership, management, training and governance structures

- *Operational management with clear decision making structures and an appropriate balance of skills/responsibilities (e.g. project management, data management and access, sample maintenance, fieldwork, etc.)*
- *Scientific leadership with vision, credibility, and succession planning, within clear decision making structures*
- *An engaged external advisory mechanism with a clear purpose, which is actively used for scientific advice and horizon scanning, with membership of the advisory mechanism justified*

Criterion 3: Effective recruitment, and rigorous data and sample quality

- *Robust ethical oversight should be in place with ongoing engagement and appropriately phrased consent that is not too complicated*
- *Participants should be representative as appropriate to the scientific purpose of study, and attrition rates closely monitored to ensure that the resource remains scientifically useful*
- *Collection of samples should be well justified and, where possible, all sample and assay handling should be performed in accredited facilities according to ISO standards. Where this is not possible, LPS should seek to achieve standards equivalent to those of accredited units.*
- *All data should be obtained/linked using defined ethical, clinical and industry standards where available, and should be stored in accredited facilities with appropriate backup procedures. Where relevant, measures to ensure the security of shared data should also be in place.*
- *A clear, transparent and justifiable policy with regard to return (or not) of findings to individual participants, and this should be clearly articulated to participants.*

Criterion 4: Organised data accessibility and sharing

- *Information about available data should be clearly described and freely available (e.g. directory, website, platform)*
- *A data access management process should be in place, which should be proportionate and transparent*
- *Optimum use of data and/or samples within the framework of an access management plan (e.g. % of approved application with narrative and turnaround time)*
- *Breadth and scope of 'Declaration on Research Assessment (DORA)' outputs*

Criterion 5: Maximised value through linkage with other data sources relevant to the scientific vision of the LPS

- *(Plans for) successful linkage to the range of data sources needed to achieve scientific vision*

- *(Plans for) the collection of appropriate consents to link to relevant data sources*
- *(Plans for) the collection of relevant data items to enable linkage with range of data sources*
- *Networks only: (Plans to) bring together data from member LPS to allow for standardised cross-LPS comparisons*
- *Networks only: (Plans to) share best practice through network*

Criterion 6: Meaningful engagement with external stakeholders (including participants, wider public, industry, policy makers and practitioners) in the research process

- *Effective two-way engagement between the study team and participants*
- *Where relevant, describe effective models of two-way engagement between the study team, the wider public, policy makers, practitioners, industry, and other LPS to maximise the impact of the resource*

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."

Further information on funding for clinical trials can be found on our website. 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.)

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

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

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

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

How have patients, patient advocacy groups or communities been involved in developing the clinical aspects of this proposal?
(300 words max.)

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

You may submit up to two 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 research 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.

For Biomedical Resource and Longitudinal Population Study applicants only:

Supporting statement from host organisation
Please upload a letter or statement from your host organisation outlining their commitment to the longer-term sustainability of the resource.

Letters of support
Please upload letters of support from user communities. You should include a summary table listing who has provided these letters.

Your letters of support should be uploaded as a single PDF file; please include the summary table at the beginning.

For Multi-user Equipment applicants only:

Supporting statement from host organisation
Please upload the supporting statement from your host organisation, signed by an appropriate senior authority, indicating how the request for equipment fits with the overall strategic context of the organisation (referring to any other current multi-user equipment applications submitted to the Trust from your organisation, if appropriate), taking into consideration regional and national contexts if appropriate.

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

You may provide up to the equivalent of one A4 page 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. Citations to preprints should state "Preprint", the repository name and the article persistent identifier (e.g DOI).

References with more than 10 authors may be shortened to et al, but please ensure that your position as author (if applicable) remains clear.

Are there any papers listed in your 'Key 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.

Scientific and technical management

Provide details of: (a) the sharing and management of the equipment, resource or technology development, including how access will be managed and prioritised (if appropriate); (b) any specialist expertise or technical support required and who will provide this; (c) proposed plans for the long-term sustainability of the equipment, resource or technology development. (1500 words max.)
Include details of how any conflicting demand for access will be managed, if appropriate. Explain how the sustainability or replacement of the resource, technology or equipment will be addressed at the end of the proposed grant period (e.g. access charges, funded as a departmental resource).

LPS core support applicants only:

Provide details of: (a) the leadership, management, training, and governance structures; (b) any specialist expertise or technical support required and who will provide this; (c) proposed plans for the long-term sustainability of the LPS. (1000 words max.)

You may attach supporting information demonstrating future sustainability, e.g. extracts from business plans. Details of any proposed management or advisory committees may also be uploaded.
You should upload any supporting information in a single PDF file.

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 next to 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?'

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.)

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?

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(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.

Contributions

Please list all financial contributions, or equivalent, provided by the host organisation or other sources. Please refer to guidance notes.

Contributor	Details of contribution	Confirmed or expected	Value	Currency
				-

For multi-user equipment grants, the Trust will normally expect the application to include a contribution from the host organisation, or other source, proportionate to the total amount requested. As a guide, we would expect a contribution of at least 10 per cent on applications costing £100,000 or more. Contributions are not limited to cash and can include appropriate benefits in kind, such as refurbishment or the underwriting of a key support post.

The Trust anticipates that the equipment will be used primarily (but not exclusively) by Trust-funded researchers. Where a significant proportion of users of the equipment are not Trust-funded, we would expect applicants to consider seeking an appropriate financial contribution from alternative sources, including other funding bodies.

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.

LPS applicants only:

Please describe your plans for engagement with external stakeholders, including participants, the communities they are drawn from, wider public audiences, industry, policy makers, practitioners, and others as relevant. This should include involvement in the research planning process as appropriate.
(1500 words max.)

You should describe your plans for a programme of work to engage each of these stakeholders, including: *(i) the vision for the programme(s), including aims, specific target audiences, activities and desired outcomes;* *(ii) experience of staff and external collaborators in engaging these stakeholders;* *(iii) how you will monitor and evaluate the activities, including success indicators;* *(iv) how the host organisation will support your work;* *(v) a high-level budget breakdown.* ***To ensure that these public engagement costs are included in the overall grant budget requested, you must include the total public engagement figure under the 'Miscellaneous costs' heading in the 'Costs requested and justification' section of the form. Please include any VAT that is irrecoverable into the total figure within the 'Miscellaneous Costs' category of the 'Costs requested' section. If you exclude VAT at the outset we may not be able to increase our funding retroactively.***

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.

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. Biomedical resource and equipment grant applicants can only apply for funding of staff necessary to run/manage the central resource or apparatus (i.e. not experimental research personnel). Support for experimental research personnel will only be considered for technology development grants.

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. This total should include known pay awards that will take place during the first year (or an assumed percentage, equivalent to the Wellcome Trust's current inflation rate, where the scheduled pay award has not yet been confirmed). 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

Animals Are you requesting animals?	

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.

If appropriate, costings can be clarified in more detail in the 'Justification for resources requested' section of the form.

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.

Animals

Animal species	Total no. to be purchased	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.

Equipment Are you requesting equipment or equipment maintenance?	

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.

Equipment to be purchased
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.

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

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.

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 Wellcome Trust-funded 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.

Applicants based in a low- or middle-income country may apply for maintenance costs for equipment originally funded by us or other sources.

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

Please provide a statement from the Director of Procurement/Head of Purchasing (or equivalent), outlining the rationale for selection of preferred manufacturer/suppliers for each piece of equipment with a list price of £100,000 or more, including a brief summary of quotes received and the level of discount negotiated (no more than 400 words).

Access charges Are you requesting access charges?	

Please refer to the scheme webpage for information on allowable access charges.

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

Travel and subsistence Are you requesting travel and subsistence?	

Items that should be detailed here can include collaborative visits and, for resource/technology applicants, attendance at scientific meetings to publicise the resource/technology.

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.

Travel and subsistence

Description	Total

Miscellaneous costs 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 'Research Management costs'); 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.

Miscellaneous other

Type	Description	Total

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

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

Justification for resources requested
Please provide a 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"; "Equipment"; "Miscellaneous".

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.

You should provide a justification for any equipment, equipment maintenance and access charges not already justified under 'Details of resource, technology development or equipment'.

Where a piece of equipment exceeds £100,000, please provide details of:

- *similar equipment in the applicant's department and adjacent departments, and the reasons why it cannot be used for the particular project(s);*
- *any other individuals likely to benefit from use of the equipment.*

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 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)

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 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).

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.

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)

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 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).

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

Will the funds on this grant be used directly for animal research?	

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

Please explain why not

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

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

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

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

Please provide details in terms of the justification for single housing, its duration, and what additional resources will be provided to the animals to minimise the impact on animal welfare.

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

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

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

Will any of the experimental procedures involve restraint?	

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

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

Will any of the staff involved require specific training for any of the procedures concerned?	

Please provide details of the training needed and where it will be undertaken.

Cats, 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.

From where will the animals be sourced?

Will it be necessary to transport the animals?	

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

Are animals to be imported?	

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

Please provide details of the housing for the animals, e.g. enclosure size, environmental enrichment.
Please see the NC3Rs guidance on animal housing and husbandry for further details: https://www.nc3rs.org.uk/3rs-resources/housing-and-husbandry

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

Please provide details in terms of the justification for single housing, its duration, and what additional resources will be provided to the animals to minimise the impact of the single housing.

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

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.)

Will any of the experimental procedures involve restraint?	

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

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

Will any of the staff involved require specific training for any of the procedures concerned?	

Please provide details of the training needed and where it will be undertaken.

Risks of research misuse

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

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.)

Freedom to operate/conflicts of interest

Describe any freedom to operate issues or potential conflicts of interest that have been identified or that might arise and how these will be or have been addressed.

In particular, please consider the following:

- Do any of the individuals involved in the project hold any consultancies or equities in, or directorships of, companies or other organisations that might have an interest in the results of the proposed activity?
- Will the proposed activity use technology, materials or other inventions that are subject to any patents or other form of intellectual property protection?
- Will any element of the activity be subject to agreements with commercial, academic or other organisations, including arrangements with collaborators named in the grant application, that might lead to intellectual property issues or restrictions?

(350 words max.)

Please describe any freedom to operate issues or potential conflicts of interest that may affect your ability to carry out the proposed project and/or to comply with the Trust's grant conditions.

Where the proposed activity, in whole or in part, is subject to agreements with commercial, academic or other organisations, e.g. Materials Transfer Agreements, the Wellcome Trust will expect a written assurance from the administering organisation that the terms of any such agreement do not conflict with the Trust's grant conditions, particularly in relation to the publication of research and the granting of research rights.

Please refer to the Wellcome Trust's website for our policy on the relationship between Trust-funded researchers and commercial entities: www.wellcome.ac.uk/funding/managing-grant/policy-relationships-between-trust-funded-researchers-and-commercial-organisations.

Details of our policy on intellectual property can be found in our Grant Conditions www.wellcome.ac.uk/funding/managing-grant/grant-conditions.

Applicants should disclose all relevant information pertinent to their grant proposal, including proprietary information where appropriate, in order to provide the most comprehensive picture of the proposed activity.

If no issues have been identified, please enter N/A.

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