Application summary

Application title
This should be the title of your proposal.

Proposed duration of funding (months)

Proposed start 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.	

Funding area Please select from the drop-down list the funding area that you consider your project falls under
Please note that, when received, we may reallocate your application to another funding area if we consider it appropriate.

Lead applicant

Lead applicant details	
Full Name	
Department	

Division	
Organisation	
Address Line 1	
City/Town	
Postcode	
Country	
Telephone No.	
Email Address	

ORCID iD	
ORCID iD	

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

Current position

Organisation

Start date of post	

Expected date of termination of post	

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 body). 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.

Are you clinically active?	

Please specify

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

Experience relevant to this proposal Please summarise your key achievements and experience which are relevant to this proposal. (350 words max.)
Please summarise what you consider to be your key achievements and experience and their relevance to this proposal; state which period of your career they relate to. You do not need to list all of your positions.

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.

Current and recent research funding (including Wellcome Trust grants) Please list all held in the last five years and any key prior grants (list the most recent first). State the name of the awarding body, name(s) of grantholder(s), title of project, amounts awarded, your role in the project, and start and end dates of support. For all active grants, indicate the number of hours per week that are spent on each project.
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 have held in the last five years, including any Wellcome Trust awards. Please state clearly your role in obtaining the awards, for example, whether you held 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.

Applicants

Applicants are expected to be actively involved in the project.

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Applicant	
Full Name	
Department	
Division	

Organisation	
Address Line 1	
City/Town	
Postcode	
Country	
Telephone No.	
Email Address	

Applicants are expected to be actively involved in the project.

Current position

Organisation

Start date of post	

Expected date of termination of post	

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 body). 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'.

Experience relevant to this proposal
Please summarise your key achievements and experience which are relevant to this proposal. (350 words max.)

Please summarise what you consider to be your key achievements and experience and their relevance to this proposal; state which period of your career they relate to. You do not need to list all of your positions.

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.

Current and recent research funding (including Wellcome Trust grants)
Please list all held in the last five years and any key prior grants (list the most recent first). State the name of the awarding body, name(s) of grantholder(s), title of project, amounts awarded, your role in the project, and start and end dates of support. For all active grants, indicate the number of hours per week that are spent on each project.

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 have held in the last five years, including any Wellcome Trust awards. Please state clearly your role in obtaining the awards, for example, whether you held 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.

Summary

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

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.

The proposal

Please provide details of your proposal. These should include:

- Aims and key deliverables;
- Background and justification;
- Details of the planned activities;
- Timetable and milestones (as appropriate).

In addition, please ensure that you provide any further specific information requested by your Wellcome Trust contact.

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.

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

Figures, graphs, tables, if essential to the proposal, should be embedded in the text. Other additional essential

information can be uploaded separately, for example: references, unpublished data, letters of support. The additional information should not be an extension of the proposal.

Any references provided must be 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.

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).

Research-related proposals

Approach and methods to be used in investigating this problem
Details of experimental design for animal studies should be provided as part of the justification for animals in the 'Budget 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.

Clinical trials applications
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."

Ensure that your proposal includes the following:

(i) Contributors
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.

(ii) Study design
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.

(iii) Inclusion/exclusion criteria
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?

(iv) Outcome measures
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.

(v) Sample size
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.

(vi) Patient and community engagement
How have patients, patient advocacy groups or communities been involved in developing the clinical aspects of this proposal?

(vii) Governance and monitoring
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?

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 the trial within this application form.

Proposal management, including team composition where relevant Describe how the project will be managed and led and the roles of any applicants. (500 words max.)

Does your proposal involve human participants?	

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.

Details of studies involving human participants including clinical trials

Describe the study design. This should include, as applicable: • number of participants in each group; • type, frequency and duration of interventions and/or health outcome measures; • frequency and duration of planned follow up; • any other activity with potential significant risks to participants; • details of any investigational product, focusing on manufacture, quality and consistency. (300 words max.)

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

- *screening procedures*
- *collection of biological samples*
- *biometric and clinical data*
- *experimental challenges*
- *behavioural treatments*
- *process-of-care-changes*

What are the primary and secondary outcome measures, and how will you assess these? (200 words max.)

Outline the strategy for recruitment and describe the inclusion/exclusion criteria for study participants (if applicable). What are the proposed arrangements for allocating participants to study groups? (200 words max.)

Detail and justify the power calculation, sample size and proposed statistical analysis, including any interim analyses and/or subgroup analyses. What are the proposed methods for protecting against sources of bias? (200 words max.)

Describe the supporting personnel and infrastructure that will be used to deliver the proposed research (for example key support staff, roles of team members, participating centre(s) or facilities). Detail any activity a third party is undertaking, and explain what agreements or formal contracts will be in place. (200 words max.)

How have you involved patients, participants, patient advocacy groups or communities in developing this proposal? (200 words max.)

You may upload essential additional information in support of your proposal (e.g. Gantt charts, graphs, figures, tables)
Additional information
-

Public engagement

Do you have plans for engaging with the public about your work?	
The Wellcome Trust is committed to engaging with society about the research it supports. Further information is available on the Wellcome Trust's website. *We expect those 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.

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?'

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 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

Budget 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.

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: "Postgraduate research assistant", "Postdoctoral research assistant", "Technician", "Fieldworker". Please specify the level of seniority of the post where relevant, e.g. "Junior postdoctoral research assistant", "Senior postdoctoral research assistant"*

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

Justification for personnel requested, specifying their role and responsibilities. (500 words max.)
Please give a justification for the type and seniority, including the level of salary requested, of each post sought. This information should also be provided where requests are made for replacement lecturers' and applicants' salaries. *Where staff requested will be working in different locations, please indicate where they will be working.*

Materials and consumables Are you requesting materials and consumables?	

Materials and consumables

Description	Total

Justification for materials and consumables requested (500 words max.)

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. *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.

Justification for animal costs requested (500 words max.)

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.

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. 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.

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.

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. 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.

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.

Justification for equipment and equipment maintenance requested. (500 words max.)
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 this particular project;* • *any other individuals likely to benefit from use of the equipment.*

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.*	

Access charges Are you requesting 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**

Justification for access charges requested. (300 words max.)

Travel and subsistence Are you requesting travel and subsistence?	
This can include conference attendance and collaborative visits.	

Travel and subsistence

Description	**Total**

Justification for travel and subsistence costs requested. (300 words max.)

Miscellaneous costs Are you requesting miscellaneous costs as part of this application?	
Costs that do not fall under any other category should be included in this section, for example, overseas allowances. *Working abroad* *Where the application involves carrying out research abroad, overseas allowances may be requested for the applicant(s) and/or research staff to be employed on the grant.* *Overheads* *Where overheads are allowed and are being requested, you will need to provide a letter from the Finance Director of your organisation. The letter should provide a breakdown of the costs requested and confirm that the request is a true representation of the costs incurred.*	

Miscellaneous other

Type	**Description**	**Total**

Justification for miscellaneous costs requested. (500 words max.)

Summary of financial support requested	
	Total
Total	

Are you requesting overheads under the miscellaneous costs heading? (for small charitable or not-for-profit organisations, or low- and middle-income country organisations only)	

Please upload a letter from the Finance Director of your organisation. This letter should provide a breakdown of the costs requested and confirm that the request is a true representation of the costs incurred.

Proposals 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 (as defined in the Data Protection Act 2018) is any information relating to an identified or identifiable living person i.e. a person who can be identified either directly from that information or indirectly by combining it with other available information. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available at: http://www.highlights.rsc.mrc.ac.uk/PIHR/index.html#/?_k=opxohv and https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/.

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 (as defined in the Data Protection Act 2018) is any information relating to an identified or identifiable living person i.e. a person who can be identified either directly from that information or indirectly by combining it with other available information. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available at: http://www.highlights.rsc.mrc.ac.uk/PIHR/index.html#/?_k=opxohv and https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/.

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).

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 project.

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. The Wellcome Trust cannot act as sponsor.	

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).

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

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

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.

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 activity 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/guidance/guidelines-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