Application summary

Application title This is the title of your proposal.

Proposed duration of funding (months)

Proposed start date	

Name of administering organisation If your application is successful, this is the organisation that will be responsible for administering the award.

Lead applicant's address at administering organisation If your application is successful, we will use this address in your award letter.	
Department/Division	
Organisation	
Street	
City/Town	
Postcode/Zipcode	
Country	

Funding area Select the most relevant area, based on the key aims of the project. This allocates your application to the relevant Grants team. We may reallocate your application to another 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	

Current position

Organisation

Start date of post	

Expected date of termination of post	

Source(s) of personal salary support State all your sources of salary funding (for example, through your organisation's block grant from a higher education funding body), and the percentage of your salary they contribute. Answer 'not applicable' if you are not currently employed.

Your source of salary may affect your eligibility.

If your source of salary places any restrictions on intellectual property rights or publications arising from your research, contact us as this may also affect your eligibility.

Clinical status Are you a healthcare professional?	

Indicate your healthcare profession

Are you clinically active?	

What is your specialty? If your specialty is not on the list, select 'Other' and specify.

Specify

Experience relevant to this proposal 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. (350 words max.)

Career contributions What are your most important research-related contributions? These may be from any stage of your research career. State what each contribution was, when it came about, why you think it is important and what impact it has had. Examples include publications, patents and impacts on policy. (350 words max.)

Current and recent research funding (including Wellcome grants) List all research funding you have held in the last five years and any key funding before then. List the most recent first. State the name of the funder, name(s) of grantholder(s), title of the project, total amount awarded (and how much of this you received), your role in the project, and the start and end dates. State the percentage of your time spent on the research; if the grant is active state the number of hours per week that you spend on the research.
Include details of any recurrent or core funding you have held. Explain your role in obtaining the funding. For example, whether you held them in your own right as lead applicant, coapplicant, or as part of a consortium. *We look at your success in getting research funding when we assess your track record. We also want to understand how this proposal is distinct from other funding you hold.*

Applicants

Applicants are expected to be actively involved in the project.

1

Applicant	
Full Name	
Department	
Division	
Organisation	
Address Line 1	
City/Town	
Postcode	

Country	
Telephone No.	
Email Address	

Current position

Organisation

Start date of post	

Expected date of termination of post	

Source(s) of personal salary support
State all your sources of salary funding (for example, through your organisation's block grant from a higher education funding body), and the percentage of your salary they contribute. Answer 'not applicable' if you are not currently employed.

Your source of salary may affect your eligibility.

If your source of salary places any restrictions on intellectual property rights or publications arising from your research, contact us as this may also affect your eligibility.

Experience relevant to this proposal
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.
(350 words max.)

Career contributions
What are your most important research-related contributions? These may be from any stage of your research career. State what each contribution was, when it came about, why you think it is important and what impact it has had. Examples include publications, patents and impacts on policy.
(350 words max.)

Current and recent research funding (including Wellcome grants)
List all research funding you have held in the last five years and any key funding before then.

List the most recent first. State the name of the funder, name(s) of grantholder(s), title of the project, total amount awarded (and how much of this you received), your role in the project, and the start and end dates. State the percentage of your time spent on the research; if the grant is active state the number of hours per week that you spend on the research.

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

We look at your success in getting research funding when we assess your track record. We also want to understand how this proposal is distinct from other funding you hold.

Summary

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

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

We will use this as a short abstract and to classify your proposal by subject. We may edit your summary and then use it to describe your research on our website and elsewhere (we publish summary details of all our awards).

The proposal

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

If you do not understand any part of this guidance, contact us for advice. Provide all relevant information within the application form; do not refer to additional unpublished information on personal websites.

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

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

You must cite any references 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). You may shorten references with more than 10 authors to et al, but please ensure that your position as author (if applicable) remains clear.

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

Research-related proposals

Approach and methods to be used in investigating this problem
You should detail experimental design for animal studies in the 'Proposals involving animals' section.

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. Give particular attention 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 (for example Gantt charts, graphs, figures, tables).
Additional information
-

Public engagement

How could members of the public and non-academic communities, inform, use, or find value in your research? (250 words max.)
We want to foster a culture that values, recognises and better supports public engagement with research. Successful applicants are encouraged to apply for additional funds to support their engagement plans through our Research Enrichment scheme. Further information on the scheme and on Wellcome's approach to public engagement is available on our website. *Engagement that is essential for the ethical conduct of your research, such as patient information leaflets or community advisory boards, should be part of your research methodology. You should include costs for this within your main research costs.*

Have you discussed your ideas and plan with your institutional Public Engagement Officer (if you have one?)	
Answers to this question are for monitoring purposes only. You will not be penalised for answering 'no'. However, we strongly recommend you utilise any institutional public engagement support available in planning your approach.	

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?	
Our Data, Software and Materials Management and Sharing Policy states that all Wellcome-funded researchers must 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.	

Select the approach you will use to maximise the impact of your significant research outputs to improve health and benefit the wider research community.

Provide an outputs management plan

Our guidance on developing an outputs management plan sets out where such a plan is required and gives an overview of what you must consider. (700 words max.)
Your plan must be clear, concise, proportionate and focus specifically on how you will identify outputs, manage these and then use them to advance potential health benefits. 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.* *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.*

Location of activity

Will the funded activity take place at more than one location? List any locations outside of your administering organisation where you will be conducting research or redirecting funds. This includes, but is not limited to, anywhere in receipt of indirect funding, fieldwork sites, and time spent working in another organisation/laboratory. This does not include conference attendance.	

For each location, select the country and, where applicable, state the organisation. You must include the administering organisation.
Enter the approximate percentage of the total funds that will be spent in each location. Enter zero for locations where activity will take place but no significant funds will be spent. If you are requesting salary costs, attribute them to the employing organisation.

Country	Organisation	Percentage of funds

Budget and justification

Select the currency in which you want to apply Submit costs in the currency you think will best enable you to undertake the activity. This will probably be your local currency; if not, explain why not.
If you think that the currency may not be readily available, email grantpayments@wellcome.ac.uk. For more information

see our website.

If we cannot award in the currency requested, we will talk to your administering organisation about using another.

Is this your local currency?	

What is your local currency?	

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

Salaries Are you requesting salaries? For details of what staff costs you can request and how to cost salaries, refer to the guidance notes for this question. You can also check our guidance on costs grantholders can claim.	

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

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

Definition of terms

Staff category: *For example: "Postgraduate research assistant", "Postdoctoral research assistant", "Technician", "Fieldworker". 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 must be quoted on a pro rata basis.*

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

Salaries / Stipends

Total

Justification for salaries requested Specify the role and responsibilities for the staff requested. Justify the type and seniority, including the level of salary requested, of each post. You must also provide this information for any requests for replacement lecturers' and applicants' salaries. (500 words max.)

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

be allocated.

Are you requesting salary recovery? You can request salary recovery for applicants if: • they are spending at least 10% of their working time on the project and • they hold an established position and • they are required to seek partial or full salary support from external grant funding. If you answer yes, we will ask you to upload a letter from a senior member of **each organisation confirming these points**.	

Upload a letter from a senior member of **each organisation** requesting salary recovery. If there is more than one letter, upload these as a single PDF.
Check the guidance notes for this question for details of what the letter must contain.

The letter must confirm that:

- *the applicant will be spending at least 10% of their working time on the project;*
- *the amount of salary requested is proportionate to the amount of working time spent on the grant;*
- *the reason why they are required to seek partial or full salary support from external grant funding. Either that:*
  - the employment contracts of the applicants stipulate that their salaries must come from external grant funding, and the host organisation will not guarantee these salaries if applicants are not successful in getting it from external sources;
  or
  - it is the policy of the organisation that salary recovery costs must be included in all grant applications for staff who hold a permanent, open-ended or long-term rolling contract.

Materials and consumables Are you requesting materials and consumables?	

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

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

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

Materials and consumables

Total

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

Animals Are you requesting animals?	

In order to ensure animal experimentation costs are accurate, you must complete this section after consultation with your animal house or biological services manager. We require your organisation to apply a consistent costing methodology when presenting cost details.

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

Animals

Total

Associated Costs

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. (500 words max.)
Do not include a justification of the animal numbers you require; you can explain this 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) must be aware of all potential capital purchases and we require organisations to use best procurement practice when purchasing equipment with Wellcome Trust funds. ***Equipment to be purchased*** *We expect you to consider the cost-effectiveness of the proposed purchase of equipment. The estimated price of the equipment must cover all aspects including delivery, installation, maintenance and training, where appropriate. We expect discounts to be negotiated and included in quoted prices.* *We normally expect a contribution from the host organisation, or other source, where the application includes a substantial equipment request. If you have any questions about this, check with your Wellcome contact.* *If there is a preferred manufacturer for certain items of equipment, you can explain this in the 'Type of equipment' field.* *We expect that the equipment you request will be covered by the manufacturer's warranty for the first year after it is purchased. We 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. We will also consider costs for the maintenance of equipment over 5 years old if you can demonstrate that it is cost-effective.* *Value Added Tax (VAT)* *For grants to be held in the UK, the costs of all equipment to be used for medical and veterinary research must be quoted exclusive of VAT. For equipment that does not fall within this definition, VAT costs should be shown.*	

Equipment

Total

Equipment maintenance

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

Justification for equipment and equipment maintenance costs. (500 words max.)

If you are requesting a piece of equipment which costs more than £100,000, provide details of: • *similar equipment in the applicant's department and adjacent departments;* • *why it cannot be used for this particular project; and* • *any other individuals likely to use the equipment.*

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

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

Synchrotron radiation sources Will you need access to a synchrotron source?	
We collect data on access to synchrotron sources for information purposes. *Apply directly to the synchrotron facility you want to use.*	

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

Specify:

Are you requesting costs from us relating to synchrotron radiation sources?	
These facilities are normally free for researchers who are prepared to publish their results in the public domain. If this is not the case, you can request access costs in the 'Access charges' section. You can also request related costs for travel and subsistence in the 'Travel and subsistence' costs section.	

Access charges Are you requesting access charges?	

Access charges

Total

Justification for access charges. (300 words max.)

Travel and subsistence Are you requesting travel and subsistence costs? This can include conference attendance and collaborative visits.	
Include conference attendance, collaborative visits and other travel related to this grant separately. Where necessary,	

please state the host organisation. Find out more about our carbon offset for travel policy here.

Conference attendance
The lead applicant and any research staff to be employed on the grant can request costs to attend academic/scientific conferences, including conference registration fees and carbon offsetting the travel, up to a maximum of £2,000 a year for the lead applicant and £1,000 a year for research staff. Specify the amount being requested per person and tell us how you calculated any carbon offset costs.

Collaborative visits
If you are requesting costs for collaborative visits, state the host organisation and provide a detailed breakdown of the travel and subsistence costs. You can include the cost of carbon offsetting the travel involved. Justify the need for each visit, its duration and your mode of transport separately, and tell us how you calculated any carbon offset costs.

Other travel related to this grant
You can request costs for other essential visits, for example for sample collection and trips to facilities. You can include the cost of carbon offsetting the travel involved. Justify the need for the visit, its duration and your mode of transport separately, and tell us how you calculated any carbon offset costs.

Travel and subsistence

Total

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

Miscellaneous costs Are you requesting miscellaneous costs?	

Provide a detailed breakdown of the miscellaneous costs requested. Enter costs that do not fall under any other category in this section.

Working abroad
If costs are requested for the applicant(s) and/or research staff to be employed on the grant to carry out any of the proposed research abroad, state the overseas host organisation, and detail the travel costs and other overseas allowances. Allowances should be itemised. If you have any questions about this, check with your Wellcome contact.

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

Miscellaneous other

Total

Justification for miscellaneous costs. (500 words max.)

Summary of costs requested	
	Total

Total	

Are you requesting overheads under the miscellaneous costs heading?	

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

Each letter must include:

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

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

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

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."

Our policy position on research involving human participants can be found on our website.

We require ethical approval (usually from the appropriate National Health Service (NHS) research ethics committees) for all research we fund 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/.

You should seek approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority (HFEA) or the Gene Therapy Advisory Committee in the UK where necessary, 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, you should seek this 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).

Confirm that you have read our guidance on the feedback of health-related findings in research (available on our website) and that you are in the process of considering your approach to this.

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

Do you propose to use facilities, staff or patients within the National Health Service (NHS) in the UK?	

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. The Wellcome Trust cannot act as sponsor.

Have you completed a Schedule of Events Cost Attribution Tool? This must be signed off by an AcoRD specialist. Download a template SoECAT here. See our webpage on Clinical research using NHS facilities for more information.	

Explain why you have been unable to complete a Schedule of Cost Attribution Tool.
You can submit your SoECAT whilst we are reviewing your application but Wellcome cannot make a funding decision without it. If you do not have a signed off SoECAT form your research will not receive HRA approval (or equivalent).
(100 words max.)

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?	

Which organisation(s) have agreed to fulfil this role? The Wellcome Trust cannot act as sponsor.

Confirm you have in place or you will seek appropriate informed consent to use any potentially commercially exploitable results from tissues or samples derived from human participants.

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

Select any of the following that apply to your proposed work:
(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 our website.

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

- *the complete replacement of live animals with tissues derived from either animals or humans;*
- *the possibilities of reducing the numbers of animals that need to be used;*
- *refining the experimental design 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 (for example, 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 about the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), see www.nc3rs.org.uk

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

Select any of the following species you will use:
(Primate, Cat, Dog, Equidae, Pig, Genetically Altered Animals, Other animals)

The NC3Rs will review all applications involving the use of primates, cats, dogs and equidae animals, or their tissue/data.

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

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

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

Provide a justification of the proposed sample size alongside details of the planned statistical analyses. Describe experimental design, including any plans to reduce bias such as blinding or randomisation if appropriate. You must include power calculations if appropriate. (1,000 words max.)

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

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

- *definition of unit of analysis (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.*

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

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

Is there a current Home Office Personal Project Licence (PPL) that authorizes the proposed procedures to be carried out in the UK?	

Provide the name of the licence holder and the PPL number.

Detail your plans and timelines for acquiring the appropriate licence.

If your proposal involves the use of animals, what would be the severity of the procedures? You can find guidance on assessing the severity of a procedure on the Home Office website.

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?	

Confirm that the proposed animal work outside of the UK will comply with the principles of UK law. Animal research conducted outside the UK must, as a minimum standard, be carried out in accordance with the principles of UK law and regulation. (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.

You should refer to NC3Rs guidance on carrying out work abroad and choosing contractors.

Why is animal use necessary: are there any procedures of less severity that could be used? (250 words max.)

Non-human primates If you are exclusively using already generated tissue or data in the proposed experiments answer all relevant questions as thoroughly as possible, in particular the questions relating to housing and procedures. If a question is not relevant you can answer 'N/A', but 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' ?	

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.

Provide details of the housing for the animals, e.g. enclosure size, environmental enrichment.
See the NC3Rs guidance on animal housing and husbandry for further details.

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

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

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 will you require of the staff named in the application? What provision are you making for continuing professional development in these areas?

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

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 answer all relevant questions as thoroughly as possible, in particular the

questions relating to housing and procedures. If a question is not relevant you can answer 'N/A', but 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.

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?	

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

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

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.

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 you require of the staff named in the application? What provision are you making for continuing professional development in these areas?

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

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

Risks of research misuse

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

Wellcome encourages 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. These 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*

Have you identified any tangible risks of this type?	

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

*Where you judge there are **tangible** (real and non-hypothetical) risks that the proposed research **will itself** generate outcomes that could be misused to cause harm, you (and your fellow researchers and host organisations) must take appropriate steps to monitor the research as it proceeds and minimise these risks. Risk mitigation could include establishing a process to review dual use risks on an on-going basis through the project and to gain independent expert advice as appropriate. You must also ensure that all members of your team are aware of these risks in progressing their research, and receive appropriate education and training on these issues.*

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.

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

Carbon offset for travel

Are you requesting costs to offset the carbon emissions involved in your travel?	
How much are you requesting for carbon offset costs ()?	
How much carbon will this offset (in tonnes)?	
Are you requesting costs for alternatives to travel, so you can travel less?	
How much are you requesting for these alternatives ()?	
How much carbon will you save by using alternatives to travel (in tonnes)?	

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?	

Specify